## 1 1 UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF CALIFORNIA 2 BEFORE THE HONORABLE ANTHONY J. BATTAGLIA, JUDGE PRESIDING 3 IN RE INCRETIN-BASED THERAPIES ) CASE NO. 13-MD-02452-AJB 4 PRODUCTS LIABILITY LITIGATION, 5 -----) SAN DIEGO, CALIFORNIA 6 2:03 P.M. 7 AS TO ALL RELATED AND MEMBER CASES ) MARCH 12, 2015 8 9 REPORTER'S TRANSCRIPT OF PROCEEDINGS 10 RE: MOTION HEARING 11 12 13 14 TELEPHONIC APPEARANCE: HONORABLE WILLIAM F. HIGHBERGER 15 OFFICIAL REPORTER: JEANNETTE N. HILL, C.S.R. 16 U.S. COURTHOUSE, 333 WEST BROADWAY, RM 420 SAN DIEGO, CALIFORNIA 92101 17 (619) 702-3905 18 REPORTED BY STENOTYPE, TRANSCRIPT PRODUCED BY COMPUTER 19 2.0 21 22 23 24 25 MARCH 12, 2015

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1	FOR THE PLAINTIFFS:		
2		HUNTER J. SHKOLNIK NAPOLI BERN RIPKA SHKOLNIK LLP EMPIRE STATE BUILDING	
3		350 FIFTH AVENUE NEW YORK, NEW YORK 10118	
4 5		MICHAEL K. JOHNSON JOHNSON BECKER PLLC	
6		33 S. SIXTH STREET, SUITE 4530 MINNEAPOLIS, MN 55402	
7		MAXWELL S. KENNERLY THE BEASELY FIRM LLC	
8		1125 WALNUT STREET PHILADELPHIA, PA 19107	
9		KENNETH BRENNAN TOR HOERMAN LAW	
11		101 WEST VANDALIA STREET EDWARDSVILLE, ILLINOIS 62025	
12	TELEPHONIC APPEARANCE	:	
13		RYAN THOMPSON WATTS GUERRA LLP	
14		5250 PRUE ROAD, SUITE 525 SAN ANTONIO, TEXAS 78240	
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		MARCH 12, 2015	

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1	FOR THE DEFENDANTS:	DOLLOT A.C. MADIATM
2		DOUGLAS MARVIN PAUL E. BOEHM
3		WILLIAMS & CONNOLLY 725 TWELFTH STREET, N.W.
4		WASHINGTON, D.C. 20005
5		LOREN H. BROWN HEIDI LEVINE
6		DLA PIPER US LLP 1251 AVENUE OF THE AMERICAS
7		NEW YORK, NEW YORK 10020-1104
8		KENNETH J. KING PEPPER HAMILTON LLP
9		THE NEW YORK TIMES BUILDING  37TH FLOOR, 620 EIGHTH AVENUE
10		NEW YORK, NEW YORK 10018-1405
11		KEN ZUCKER PEPPER HAMILTON LLP
12		3000 TWO LOGAN SQUARE EIGHTEENTH AND ARCH STREETS
13		PHILADELPHIA, PENNSYLVANIA 19103-2799 RICHARD GOETZ
14		HOUMAN EHSAN O'MELVENY & MYERS LLP
15		400 SOUTH HOPE STREET LOS ANGELES, CALIFORNIA 90071
16		AMY LAURENDEAU
17		O'MELVENY & MYERS LLP 610 NEWPORT CENTER DRIVE, 17TH FLOOR
18		NEWPORT BEACH, CALIFORNIA 92660
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		MARCH 12, 2015

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1	SAN DIEGO, CALIFORNIA; THURSDAY, MARCH 12, 2015; 2:04 P.M.
2	DEPUTY CLERK: CALLING MATTER TWO ON CALENDAR, CASE
3	NUMBER 13MD2452, IN RE: INCRETIN MIMETICS PRODUCTS LIABILITY
4	LITIGATION.
5	THE COURT: ALL RIGHT. WELL, GOOD AFTERNOON TO ALL
6	OF YOU. WE HAVE A GROUP HERE IN THE COURTROOM AND A GROUP ON
7	THE PHONE.
8	DID EVERYONE IN THE COURTROOM SIGN IN ON SIGN-IN
9	SHEET?
10	MR. SHKOLNIK: YES, YOUR HONOR.
11	THE COURT: ANYBODY NOT?
12	OKAY. RATHER THAN GO THROUGH THE LINEUP, WE'LL MAKE
13	THAT ATTACHMENT TO THE RECORD FOR THAT THAT PERSONALLY
14	APPEARED. AND I HAVE A LIST OF 49 OTHER NAMES FOR THE PEOPLE
15	ON THE TELEPHONE, AND WE'LL NOTE THAT AS THE APPEARANCES BY
16	PHONE.
17	AND THEN ANYONE SPEAKING IN COURT OR BY PHONE SHOULD
18	IDENTIFY THEMSELVES, IN ADDITION TO THEIR COMMENTS, SO WE CAN
19	KEEP TRACK.
20	JUDGE HIGHBERGER, AS I UNDERSTAND, WILL BE JOINING
21	LATER IN THE AFTERNOON WHEN HE IS FREE.
22	JUDGE, ARE YOU ON THERE NOW?
23	JUDGE HIGHBERGER: I'M HERE, LISTENING. I'M NOT
24	AVAILABLE AFTER 3:30.
25	THE COURT: OKAY. GREAT. SO WE HAVE THE MOTION TO

MARCH 12, 2015

DISQUALIFY EXPERT FLEMING. I HAVE A TENTATIVE RULING ON ONE ISSUE, WHICH I'LL SHARE, AND THEN SOME QUESTIONS ON THE ISSUES THAT ARE REALLY DETERMINATIVE IN LARGE PART.

AND AFTER WE WADE THROUGH ALL OF THAT, I WILL CERTAINLY GIVE THE SIDES A CHANCE TO SAY ANY OTHER COMMENTS.

FROM THE TENTATIVE STANDPOINT, I DON'T FIND THAT THE DEFENSE WAIVED THEIR RIGHT TO BRING THE MOTION OR DELAYED UNNECESSARILY HERE. I THINK IF IT WERE A SITUATION LIKE THE SALIENT OR ON-POINT AUTHORITY THAT THE PLAINTIFFS QUOTED ABOUT THE EIGHT-MONTH DELAY, THAT WOULD BE ONE THING.

AND HERE, I GUESS, BY ANALOGY, HAD THE PLAINTIFFS
DISCLOSED MR. FLEMING'S INVOLVEMENT AND THE DEFENSE THEN HAD
WAITED UNTIL AFTER THE REPORT, I MIGHT SEE IT DIFFERENTLY. BUT
I DO FIND NO WAIVER TO HAVE OCCURRED.

AS FAR AS THE ISSUES ON CONFIDENTIALITY, AND THEN DOVETAILING INTO PREJUDICE, LET ME ASK, FROM THE PLAINTIFFS' STANDPOINT, MR. FLEMING -- OR PERHAPS IT'S DR. FLEMING, TO BE FAIR TO HIM -- IS NOTED IN THE DIALOGUE HERE AS A PREEMPTION EXPERT. THE REPORT HE HAS SEEMS TO GO ON PERHAPS TO THINGS BEYOND JUST THAT QUESTION, BUT THAT MAY BE A MATTER OF DEBATE.

BUT ASSUMING I DENY THE DISQUALIFICATION ISSUE -WELL, LET ME BACK UP. ASSUMING I FIND THERE IS NO PRESUMPTION
HERE, WOULD THERE BE ANY OTHER USE FOR DR. FLEMING IN THE CASE
FROM THE PLAINTIFFS' SIDE, OR IS HIS ROLE SOLELY GOING TO BE
PREEMPTION?

1	MR. JOHNSON: YOUR HONOR, GOOD AFTERNOON. MICHAEL
2	JOHNSON ON BEHALF OF THE PLAINTIFFS.
3	THE COURT: YES, SIR.
4	MR. JOHNSON: YOUR HONOR, YES. THERE WOULD BE A ROLE
5	IN THIS CASE FOR DR. FLEMING, AND THAT WOULD BE AS AN
6	ENDOCRINOLOGIST.
7	THE COURT: OKAY. AND WOULD THAT BE WITH REGARD TO
8	GENERAL CAUSATION ISSUE, OR ARE WE TALKING ABOUT WHEN WE GET
9	ULTIMATELY DOWN TO MORE INDIVIDUALIZED CAUSATION ASSESSMENT OF
10	THE VARIOUS PLAINTIFFS?
11	MR. JOHNSON: YOUR HONOR, I WHOLEHEARTEDLY APOLOGIZE.
12	COULD I ASK YOU TO REPEAT THE QUESTION?
13	THE COURT: OH, SURE. HE WOULD BE A POTENTIAL EXPERT
14	ON ENDOCRINOLOGY IN WHAT RESPECT GENERAL CAUSATION, SPECIFIC
15	CAUSATION, OR A COMBINATION OF ALL THE ABOVE?
16	MR. JOHNSON: WITH RESPECT TO GENERAL CAUSATION, YOUR
17	HONOR. AND ALTHOUGH WE AREN'T AT THAT POINT YET, BUT IT IS
18	FORESEEABLE THAT HE COULD BE USED FOR SPECIFIC CAUSATION, AS
19	WELL.
20	AND I DID JUST WANT TO CLARIFY MY EARLIER ANSWER, AS
21	WELL. IN ADDITION TO USING HIM AS AN ENDOCRINOLOGIST IN THE
22	FUTURE, AND IN ADDITION TO PREEMPTION, HE WOULD ALSO BE USED AS
23	A GENERAL EXPERT WITH RESPECT TO FDA REGULATORY AFFAIRS. THAT
24	MIGHT BE OUTSIDE OF THE SCOPE OF JUST PREEMPTION.
25	THE COURT: FAIR ENOUGH. I APPRECIATE YOU QUALIFYING

THAT. AND WHILE I HAVE YOU AT THE PODIUM, IN THE STATEMENT OF
FACTS THAT WERE SUBMITTED AND IF YOU ARE NOT THE RIGHT
PERSON TO RESPOND FROM THE PLAINTIFFS' SIDE FEEL FREE TO YIELD
AND THIS IS NOT A LITERAL QUOTE; IT'S A PARAPHRASE.

BUT ISSUES WITH PANCREATIC CANCER INVOLVED IN THE
LITIGATION DID NOT ARISE UNTIL AFTER DR. FLEMING'S CONSULTING
WORK WITH NOVO WAS DONE. AND MY QUESTION IS WHAT DOES THAT
MEAN, THE ISSUES DIDN'T ARISE? NO ONE HAD CLAIMED OR ALLEGED A
RELATIONSHIP BETWEEN THE DRUG AND THE ONSET OF PANCREATIC
CANCER, OR THERE HAVE BEEN NO DISCUSSIONS ABOUT ANY POTENTIAL
RISK FACTOR IN ANY REGARD, OR WHAT?

MR. JOHNSON: YOUR HONOR, I AM GOING TO ACTUALLY TURN
THAT OVER TO ONE OF MY COLLEAGUES.

THE COURT: FAIR ENOUGH.

MR. KENNERLY: YOUR HONOR, GOOD AFTERNOON. MAX
KENNERLY FOR THE PLAINTIFFS. I WROTE THAT SENTENCE.

THE COURT: OKAY.

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MR. KENNERLY: SO WHAT I MEANT BY THAT WAS -- NOW, I ALSO DEPOSED MICHELLE THOMPSON, THE REGULATORY AFFAIRS OFFICER FOR NOVO. WHAT WAS MEANT BY THAT IS IF WE'RE ASKING THE QUESTION WHAT DID DR. FLEMING LEARN WHEN HE WAS CONSULTING FOR NOVO, WE HAVE TO START WITH WELL, WHAT WAS NOVO LIKELY TO TELL HIM, WHAT DID NOVO TELL HIM.

AND WE HAVE TWO DIFFERENT TYPES OF RESPONSES. ONE IS THEY HAVEN'T SHOWN ANYTHING THEY SPECIFICALLY TOLD HIM.

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	SECOND,	THE REASO	N WE PUT	THAT IN	THERE	IS T	HERE	IS
NO REASON	TO EVEN	ASSUME OR	START TO	) BELIEVE	E THAT	THEY	COUL	JD
HAVE TOLD	HIM ANY	THING ABOU'	T PANCREA	ATIC CANO	CER.			

MICHELLE THOMPSON, WHEN I DEPOSED HER, ONE OF THE QUESTIONS I ASKED HER SPECIFICALLY WAS HAVE YOU EVER COMMUNICATED WITH THE FDA ABOUT PANCREATIC CANCER? AND HER ANSWER WAS NO, I HAVE NOT.

I ASKED HER WELL, HOW DO YOU DETERMINE HOW YOU'RE
GOING TO CHANGE YOUR WARNINGS RELATING TO PANCREATIC CANCER?
SHE TOLD ME THIS ORIGINATED OUTSIDE OF THE UNITED STATES, IN AN
OFFICE IN DENMARK. AND SHE COULD PUT NO TIME LINE ON WHEN THEY
FIRST STARTED LOOKING AT IT. NOVO, TO THIS VERY DAY, CONTINUES
TO MAINTAIN THERE IS NO ISSUE WITH PANCREATIC CANCER.

SO OUR POINT IN ARGUING THAT IS WE THINK IT'S WRONG
AS A MATTER OF LAW FOR THIS COURT TO PRESUME THERE IS
CONFIDENTIAL INFORMATION BEING EXCHANGED TO HIM. THE CASE LAW
SAYS THE OPPOSITE. BUT OUR POINT THERE IS EVEN IF THE COURT
DOES SUCH PRESUMPTION OF "WELL, HE'S TALKING WITH PEOPLE, HE
MUST BE LEARNING SOMETHING," HE WOULDN'T BE LEARNING ANYTHING
ABOUT PANCREATIC CANCER. OUR ALLEGATION IS NOVO SHOULD HAVE
KNOWN, BASED ON ITS INFORMATION.

BUT THE FACTS ARE NOVO, AT LEAST INTERNALLY, FROM
WHAT WE'VE SEEN, THEY ARE NOT HOLDING STUDIES ON THIS. THEY
ARE NOT FLAGGING IT AS AN ISSUE. AND IN NOTHING WE SAW
REFERENCING DR. FLEMING, ATTACHED TO THEIR MOTION, IS THERE ANY

REFERENCE TO AN ISSUE WITH PANCREATIC CANCER.

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SO THAT IS WHAT WE MEANT BY THAT, YOUR HONOR, IS THAT HE LEFT BEFORE THERE WAS ANY DISCUSSION, AT LEAST THAT WE KNOW OF, INSIDE OF NOVO ABOUT THAT.

THE COURT: OKAY. AND ALONG THAT SAME LINE -- AND,

AGAIN, YOU MAY YIELD TO ONE OF YOUR COLLEAGUES BECAUSE I KNOW

YOU'VE DIVIDED UP THE WORK IN MANY RESPECTS -- BUT HOW FAR BACK

DOES THE DISCOVERY THAT YOU HAVE NOW ON VICTOZA GO?

DOES IT GO BACK INTO THE '79 AND EARLIER -- OR 2009

AND EARLIER? I DON'T KNOW WHERE I GOT '70. BUT 2009 AND

EARLIER, OR IS IT THAT POINT FORWARD? IN OTHER WORDS, DOES THE

DISCOVERY OVERLAP A PERIOD IN WHICH TIME DR. FLEMING WAS

CONSULTING?

MR. KENNERLY: I'D HAVE TO YIELD, YOUR HONOR.

MR. SHKOLNIK: YOUR HONOR, HUNTER SHKOLNIK. SORRY

FOR THE BOUNCING AROUND. THERE IS NO QUESTION WE HAVE BEEN

PROVIDED DISCOVERY DATING BACK SINCE, I THINK, THE EARLY 2000S.

I'M SURE COUNSEL WILL CORRECT ME. BUT THEY GAVE US THE FULL

PACKAGE OF THE GENERAL CAUSATION AND REGULATORY MATERIALS FROM

THE INCEPTION OF THE DRUG. AND THAT WOULD CERTAINLY BE INTO

THE 2002, 2003 TIME FRAME. MAYBE ONE YEAR AFTER, ONE YEAR

BEFORE. AND IT INCLUDED 2009. AND WE'VE HAD IT RIGHT UP UNTIL

THE CUT-OFF DATE IN 2013. THANK YOU.

THE COURT: OKAY. THAT HELPS. THANK YOU VERY MUCH.

TURNING TO NOVO, WHO IS GOING TO SPEAK FOR THEM? AS

1	I LOOK AT THE CASE LAW ON THIS ISSUE OF CONFIDENTIAL
2	INFORMATION RELEVANT TO THE LITIGATION, MOST OF THE ISSUES OR
3	FACTORS THAT ARE ADDRESSED ARE THINGS THAT RELATE TO LITIGATION
4	AND THE LIKE STRATEGIES, ANTICIPATED WITNESSES, AND SO
5	FORTH. AND THE MAJORITY OF THE WORK OR CONNECTION BETWEEN
6	FLEMING AND YOUR CLIENT SEEMS TO BE THE OTHER OTHER THINGS.
7	SO I'M NOT SURE I SEE WHERE NO DOUBT A
8	CONFIDENTIAL RELATIONSHIP. I DON'T THINK THAT IS REALLY A BIG
9	ISSUE. THERE MAY BE A QUESTION ABOUT COMPETITOR ON THE
LO	SANCTIONS, BUT WE'RE DEALING NOW WITH THE CONFIDENTIAL
L1	INFORMATION.
L2	BUT OF WHAT ILK IS THAT? BECAUSE IT DOESN'T SEEM TO
L3	BE THE STRATEGIC WITNESS-RELATED TYPE OF THING, FROM WHAT I
L4	GLEANED FROM THE RECORD.
L5	MR. BROWN: OKAY. SO, YOUR HONOR, MAYBE I CAN HELP
L6	YOU WITH THE RECORD. LOREN BROWN FOR NOVO NORDISK. THANK YOU,
L 7	YOUR HONOR.
L8	FIRST, I THINK AS A GENERAL MATTER, I WOULD LIKE TO
L9	TALK ABOUT SOME OF THE THINGS HE WAS INVOLVED WITH, AND I CAN
20	POINT TO ANY ASPECTS OF THE RECORD AND THE EXHIBITS, IF THAT

TALK ABOUT SOME OF THE THINGS HE WAS INVOLVED WITH, AND I CAN POINT TO ANY ASPECTS OF THE RECORD AND THE EXHIBITS, IF THAT WOULD BE HELPFUL. AND THEN I'LL TALK ABOUT SOME SPECIFIC ISSUES THAT ARE RAISED IN HIS REPORT, WHERE HE WAS DEEPLY IN THE MIDDLE OF LONG BEFORE HE EVER DECIDED TO BE AN EXPERT IN THIS CASE.

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SO IF YOU LOOK AT THE EXHIBITS THAT WE HAVE, AND WE

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LOOK AT THE ALMOST-DECADE-LONG TIME THAT HE WAS A CONSULTA	NT
FOR NOVO NORDISK, YOU WILL SEE THAT DR. FLEMING WAS PRIVY	TO
VIRTUALLY THE DATA RELATED TO THE ENTIRE CLINICAL PROGRAM	
RELATED TO VICTOZA, THEIR PLANS AND STRATEGY RELATED TO TH	E
DESIGN OF STUDIES, HOW THE COMPANY AND OTHER CONSULTANTS W	НО
WERE SUBJECT TO CONFIDENTIAL AGREEMENTS WERE INTERPRETING	THE
DATA, THE COMPANY'S REGULATORY STRATEGY, HOW THE COMPANY	
THOUGHT ABOUT VICTOZA'S LABELING AND NOVO NORDISK INTERACT	IONS
WITH THE FOOD AND DRUG ADMINISTRATION.	

AND ALL OF THIS SHOWS THAT DR. FLEMING OBTAINED DEEP KNOWLEDGE AND INSIGHTS ABOUT VICTOZA, WHICH COULD NOT HAVE BEEN OBTAINED WITHOUT THE VIOLATION OF SEVEN CONFIDENTIALITY AGREEMENTS.

AND IF YOU WANT TO TALK ABOUT SPECIFICS THAT RELATE,
BESIDES CONSULTATION ON STUDY DESIGN, INTERPRETATION OF DATA,
REGULATORY STRATEGY, LABELING STRATEGY, THERE ARE VERY SPECIFIC
PARTS OF THE RECORD THAT GO RIGHT TO HIS CONTENTIONS IN HIS
REPORT.

ONE OF THEM IS THIS THEORY BIOLOGICALLY THAT YOU HAVE HEARD BEFORE, YOUR HONOR, THAT ALL OF THESE MEDICATIONS SOMEHOW STIMULATE THE GROWTH OF PANCREATIC BETA CELLS. THAT IS IN DR. FLEMING'S REPORT AT PAGES 43, 49, 51, AND 59.

AND IF YOU LOOK AT EXHIBITS OF OUR MOTION -- THAT IS, EXHIBITS THAT REFLECT HIS WORK WHILE CONSULTING FOR NOVO, YOU WILL SEE HOW THESE BETA CELL PROLIFERATION THEORIES WERE

DISCUSSED AT EXHIBITS 11, 12, 15, AND 16.

HE IS GETTING DEEP KNOWLEDGE AND INSIGHTS ABOUT NOVO
NORDISK'S PROGRAM DATA THAT, ACCORDING TO DR. FLEMING, SUPPORTS
HIS THEORY OF BETA CELL PROLIFERATION. AND HE IS GETTING IT IN
A WAY THAT GIVES HIM A VERY UNFAIR ADVANTAGE IN THIS CASE. AND
I WILL TALK A LITTLE BIT MORE ABOUT THAT IN A SECOND, BUT I
WANT TO POINT OUT TWO OTHER THINGS.

NUMBER TWO IS THE PLAINTIFFS' THEORY THESE DRUGS SOMEHOW INCREASE INFLAMMATION OF THE PANCREAS, CAUSE PANCREATITIS, AND THAT SOMEHOW LEADS TO PANCREATIC CANCER.

AND IF YOU LOOK AT DR. FLEMING'S REPORT, PAGES 28 TO 32, 44 AND 45, 48 AND 53, YOU WILL SEE EXTENSIVE DISCUSSIONS ABOUT THE SUPPOSED RELATIONSHIP BETWEEN THE PANCREATITIS EFFECTS OF THESE DRUGS AND PANCREATIC CANCER.

THAT'S ANOTHER SUBJECT THAT WAS PART OF DR. FLEMING'S WORK WHILE CONSULTING FOR NOVO. PANCREATITIS ISSUES WERE DISCUSSED IN EXHIBITS 15 AND 16 OF NOVO'S MOTIONS. THOSE ARE MEETINGS WHERE HE AND OTHERS WERE CALLED IN TO HELP INTERPRET DATA AND TO HELP PLAN STUDIES THAT WOULD GET AT THESE PANCREATITIS QUESTIONS.

A THIRD ISSUE, WHICH IS VERY SPECIFIC TO THIS CASE, IS THE OBSERVATIONAL STUDIES. IN NOVO'S CASE, THE OPTUM INSIGHT STUDY, WHICH IS AN OBSERVATIONAL STUDY THAT WAS INTENDED TO LOOK AT SOME OF THE SAFETY ISSUES.

AND DR. FLEMING CRITICIZES THE OPTUM INSIGHT STUDY

AND ITS DESIGN ON PAGES 73 TO 75 OF HIS REPORT, 78 TO 80, 92 TO 96, AND 98 TO 101.

NOW, WHILE HE IS CRITICIZING OPTUM INSIGHT AND ITS DESIGN, IN HIS EXPERT REPORT HE WAS SPECIFICALLY INVOLVED IN CONSULTING ON THE DESIGN OF THIS OBSERVATIONAL STUDY.

IF YOU LOOK AT EXHIBITS 15 AND 16 AGAIN, YOU WILL SEE REFERENCES TO THE DATABASE THAT WAS USED AS PART OF THIS OPTUM INSIGHT STUDY, AND HOW THE DESIGN WAS BEING DISCUSSED WITH DR. FLEMING IN THE ROOM.

SO I COULD CERTAINLY LIST MANY OTHER THINGS HE WAS INVOLVED IN -- AGAIN, GETTING INTO THE HEADS OF NOVO'S EXECUTIVES ABOUT HOW THEY THOUGHT ABOUT THESE MEDICATIONS, HOW THEY THOUGHT ABOUT SAFETY, HOW THEY THOUGHT ABOUT REGULATORY STRATEGY, HOW THEY THOUGHT ABOUT LABELING -- HE WOULD ONLY BE IN THAT POSITION BY VIRTUE OF THE FACT THAT HE VIOLATED CONFIDENTIALITY AGREEMENTS.

AND FROM A POLICY PERSPECTIVE, THAT PUTS US IN A VERY TOUGH SPOT. NUMBER ONE, IT WOULD ALLOW DR. FLEMING TO PROFIT FROM HIS BREACH OF SEVEN CONFIDENTIALITY AGREEMENTS.

BUT MORE IMPORTANTLY, IF AND WHEN WE HAVE TO TRY
THESE CASES, DR. FLEMING IS GOING TO HAVE THE BENEFIT OF
FIRSTHAND INSIGHTS, FIRSTHAND EXPERIENCES, FIRSTHAND MEETINGS,
THE BENEFIT OF CONFIDENTIAL COMMUNICATIONS, NOT ONLY FROM THE
COMPANY, BUT FROM OTHERS WHO WERE SUBJECT TO CONFIDENTIALITY
AGREEMENTS, AND HE COULD VERY WELL ENJOY A SPECIAL STATUS WITH

JURORS JUST BY VIRTUE OF HIS INSIDER STATUS IN THIS CASE. AND HE ONLY GETS THAT INSIDER STATUS AS A RESULT OF VIOLATING AGREEMENTS.

EVERY OTHER EXPERT IN THE CASE DOESN'T GET THAT

ADVANTAGE. IT PUTS US IN A TOUGH SPOT CROSS-EXAMINING HIM, AND

ALLOWS HIM TO PROFIT FROM THE BREACH OF AGREEMENTS. WHICH, AS

THE LAW SAYS -- AND AS YOUR HONOR KNOWS, IN ALL OF THE CASES,

PARTICULARLY THE ONES IN CALIFORNIA, ONE OF THE PURPOSES OF

THIS RULE IS TO PROMOTE THE INTEGRITY OF THE LEGAL PROCESS.

AND TO ALLOW HIM TO GAIN ADVANTAGE, BOTH NOW AND POTENTIALLY IN A JURY CASE, BY VIRTUE OF THE BREACH OF SEVEN DIFFERENT CONTRACTS, WOULD UNDERMINE THE INTEGRITY OF THE PROCESS.

THE COURT: AND I APPRECIATE THAT. BUT THE

INFORMATION THAT YOU CITE IN TERMS OF NOVO'S WORK -- I WON'T

RESTATE IT -- BUT THAT WOULD BE GIVEN TO ANY EXPERT, WOULD IT

NOT, FROM WHICH SIMILAR OPINIONS MIGHT BE YIELDED?

MR. BROWN: WELL, CERTAINLY THERE IS SOME OVERLAP,

YOUR HONOR. THERE IS NO QUESTION. THERE IS OVERLAP BETWEEN

THE DISCOVERY THAT THE PLAINTIFFS WERE ENTITLED TO TAKE AND THE

INFORMATION THAT DR. FLEMING WAS PRIVY TO.

HOWEVER -- OKAY -- HE HAS A SEAT AT THE TABLE WHERE

HE IS WORKING WITH AND LISTENING TO NOVO'S MOST SENIOR

SCIENTISTS, ITS CHIEF MEDICAL OFFICER, THE SCIENTIST WHO THE

PLAINTIFFS CALL THE MOTHER OF VICTOZA. IT'S GETTING DEEP

INSIGHTS ABOUT HOW THEY THINK ABOUT ALL OF THIS. SOME OF THAT IS REFLECTED IN THE DOCUMENTS; MUCH OF IT ISN'T.

BUT AGAIN, IT ALLOWS HIM TO HAVE A STATUS, ESPECIALLY IN FRONT OF JURORS, WHERE HE CAN SAY HE WAS THERE, HE WAS LISTENING TO THIS, HE WAS PART OF THAT PROCESS, HE KNOWS HOW THE COMPANY THINKS ABOUT THESE THINGS, HE UNDERSTANDS THEIR DECISION-MAKING. AND BEING ABLE TO DO THAT ONLY BECAUSE HE BREACHED AGREEMENTS IS UNFAIR.

THE COURT: AND I TAKE IT THAT MY FIRST QUESTION TO
THE PLAINTIFFS' GROUP ABOUT HIS OTHER USE IN THE CASE BEYOND
MERELY THE PREEMPTION ISSUE JUST ADDS FUEL TO THE FIRE, YOU
FEAR?

MR. BROWN: THAT WOULD MAKE IT WORSE.

THE COURT: OKAY. ALL RIGHT. WELL, THANK YOU.

ANYBODY ON THE PLAINTIFFS' SIDE WANT TO RESPOND ON
THIS? I DO THINK IT'S A SIGNIFICANT ARGUMENT ABOUT THE SPECIAL
INSIGHT THAT FLEMING HAS HAD. IT'S SORT OF AN EXTRA BOOST.
BUT YOU TELL ME.

MR. KENNERLY: YOUR HONOR, LET ME GET TO THE

INSIDER -- THE SPECIAL STATUS AT TRIAL IN JUST A SECOND BECAUSE

I THINK SOME OF THESE REQUIRE A RESPONSE.

STARTING WITH THE BETA CELL GROWTH, WE DEALT WITH
THIS ON PAGE 11, FOOTNOTE 13 OF OUR BRIEF. WIKIPEDIA TALKS
ABOUT BETA CELL INVOLVEMENT IN DIABETES. THIS IS NOT SPECIAL.
THIS IS NOT SOMETHING NOVO DEVELOPED. IT IS SOMETHING THAT

PREDATES ALL OF THE DRUGS IN THIS LITIGATION.

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THERE IS AN ARTICLE BY GIER -- WE CITE THIS IN OUR

MASTER COMPLAINT -- SAYING THAT THE HOLY GRAIL OF DIABETES

TREATMENT IS TO STIMULATE ADDITIONAL GROWTH IN BETA CELLS.

THIS IS BASIC DIABETES MEDICATION SCIENCE. IT HAS

NOTHING SPECIAL FOR NOVO. IT'S BEEN WELL-KNOWN. AND NOVO

ITSELF DISCLOSED IT AGAIN IN ITS FDA BRIEFING DOCUMENT. BUT

THIS IS NOT SOMETHING THAT WOULD BE CONFIDENTIAL TO ANYBODY.

THIS IS WHY THEY ARE ABLE TO TALK ABOUT IT WITH NO PREPARATION.

AND I THINK UNDERLYING THAT, TOO, IS DR. FLEMING WAS, QUOTE, PRIVY TO, CLOSE QUOTE, VIRTUALLY ANYTHING. WELL, NO, HE WASN'T. HE WAS GIVEN A SMALL BINDER OF MATERIALS. HE DOESN'T KNOW WHERE THOSE ARE. HE HASN'T LOOKED FOR THEM. THAT'S HIS DECLARATION. HE WASN'T GIVEN ACCESS TO THEIR SERVERS OR SCIENTIFIC INFORMATION. THIS IS WHY THEY ARE JUST BOUNCING GENERAL IDEAS OFF HIM.

MOVING TO THE THEORY OF INFLAMMATION. THIS IS ALSO
IN OUR COMPLAINT IN THIS CASE. IT'S THE THEORY THAT BUTLER
DISCUSSES, IT'S THE THEORY THAT GIER DISCUSSES, IT'S THE THEORY
THAT FRED GORELICK DISCUSSES IN HIS PRESENTATIONS. THIS IS
WELL-KNOWN. CHRONIC PANCREATITIS LEADS TO INFLAMMATION, LEADS
TO PROGRESSION OF THE PANIN NEOPLASMS, LEADS TO PANCREATIC
CANCER. THIS IS ALL WELL-KNOWN. IT'S WELL ACCEPTED IN THE
FIELD, WELL IN ADVANCE OF ANYTHING WITH THIS CASE, WELL IN
ADVANCE OF THESE DRUGS.

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TO SAY	THAT THIS IS	SOME SORT OF	SECRET THEORY THAT
NOVO DEVELOPED IS	SIMPLY WRONG	G. AND, AGAI	N, YOUR HONOR IS
CORRECT, ALL THIS	INFORMATION	WOULD GO TO	ANY EXPERT THAT WE
FOUND. IT WOULD	GO TO ANYONE	ON THE CASE.	

SIMILARLY, THE OPTUM STUDY. WE DEALT WITH THAT ON PAGE SEVEN OF OUR BRIEF. THERE IS A SHORT LITTLE DISCUSSION ABOUT WELL, WHAT DO WE HAVE TO LOOK AT TO CAPTURE SOME OF THESE EVENTS. NOW, AGAIN, THEY ARE NOT TALKING ABOUT PANCREATIC CANCER. THEY ARE JUST TALKING ABOUT EVENTS, IN GENERAL.

FLEMING HIMSELF THEN GIVES NOVO INFORMATION ABOUT
WELL, IF WE PULL IT OUT OF I3APERIO -- IT'S NOT A GREAT SOURCE
OF INFORMATION, BUT IT COULD HAVE SOME BENEFITS. HE IS NOT
WRITING THE OPTUM STUDY. HE IS NOT WRITING THE PROTOCOLS. HE
SHOWS UP FOR A DAY-LONG MEETING WHERE THEY DISCUSS A HOST OF
ISSUES. AND IN THERE THEY BOUNCE OFF OF HIM: WHAT ARE YOU
GOING TO DO WITH THE I3APERIO? HE GIVES HIS GENERAL OPINION.

THE COURT: COULD YOU SPELL THAT?

MR. KENNERLY: LOWER CASE I, NUMBER THREE, A-P-E-R-I-O.

THE COURT: THANK YOU. GO AHEAD.

MR. KENNERLY: SO, AGAIN, THEY BOUNCE AN IDEA OFF OF HIM. HE TELLS THEM HE IS THE FOREMOST EXPERT ON DIABETES REGULATION IN THE COUNTRY. HE BOUNCES BACK HIS OPINION AND THAT'S IT. THE IDEA THAT HE IS LEARNING SOME SORT OF SECRET INFORMATION FROM NOVO, BECAUSE THEY ARE CONSIDERING USING

I3APERIO, WELL, THIS IS STANDARD IN THE PHARMACEUTICAL FIELD THAT YOU WOULD LOOK AT THESE TYPE OF DATABASES. SO, AGAIN, THERE IS NOTHING SPECIAL WITH THAT.

I WILL ALMOST GET TO YOUR INSIDER STATUS IN A SECOND, BUT THERE IS ONE MORE THAT I THINK IS IMPORTANT HERE.

THE COURT: SURE.

MR. KENNERLY: THERE IS A CONSTANT ASSERTION HERE HE BREACHED HIS CONFIDENTIALITY AGREEMENT. THERE HAS NEVER BEEN ANY DESCRIPTION AS TO HOW OR WHY THEY BELIEVED THAT. I THINK THE BEST DESCRIPTION I GOT THERE WAS WELL, HE MUST HAVE. TO KNOW HOW BETA CELLS WORK IN DIABETES, HE MUST HAVE BREACHED IT. TO KNOW WHAT ISAPERIO IS, HE MUST HAVE BREACHED IT. TO KNOW WHAT INFLAMMATION IS, HE MUST HAVE BREACHED IT. WELL, THOSE ARE ALL NONSENSICAL. THOSE ARE ALL BASIC SCIENTIFIC PRINCIPLES.

HIS ACTUAL CONFIDENTIALITY AGREEMENTS, WHEN WE LOOKED AT THEM, WHEN THEY WERE FINALLY PROVIDED TO US BY DEFENDANTS, MOST OF THEM SUNSET. MOST OF THEM HAVE A TERM OF ONE YEAR ON THEM AND THEN THEY'RE DONE.

BUT I THINK AN IMPORTANT POINT HERE IS THERE IS AN ENTIRE OTHER LINE OF CASES, APART FROM HEWLET-PACKARD, ABOUT TRYING TO GET AN EXPERT WHO YOU THINK HAS ACTUALLY BREACHED A CONFIDENTIALITY AGREEMENT. DEFENDANTS THEMSELVES CHOSE NOT TO GO THAT ROUTE BECAUSE THEY KNOW THAT THERE IS NO SUPPORT BEHIND IT. THEY KNOW THERE IS NOT ONE SHRED OF EVIDENCE THAT HE HAS

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BREACHED ANY PART OF THOSE AGREEMENTS. THERE IS NOTHING HE HAS PROVIDED PLAINTIFFS. THERE IS NO INDICATION OF THAT.

SO IF YOUR HONOR WANTS TO FIND THERE IS A BREACH OF
THE CONFIDENTIALITY AGREEMENT, WHAT FACTS WOULD SUPPORT THAT?
THERE IS NO DECLARATIONS HERE FROM THE DEFENDANTS. THERE IS NO
ONE SENTENCE IN HIS REPORT THAT THEY CAN SAY MUST HAVE COME
FROM A BREACH OF CONFIDENTIALITY. THERE IS NONE THAT THEY CAN
EVEN IMPLY WENT THAT WAY, WHICH TAKES US TO INSIDER STATUS.

THIS IS NOT RECOGNIZED BY ANY OF THE AVAILABLE

PRECEDENTS. THERE IS NO CASE LAW ANYWHERE IN THE COUNTRY THAT

SAYS YOU ARE PRECLUDED FROM CALLING AN EXPERT WHO PREVIOUSLY

DID ANY WORK WITH ANY PHARMACEUTICAL COMPANY. SUCH A RULE

WOULD WREAK HAVOC ON EXPERTS IN ANY TYPE OF LITIGATION.

THE COMPANY THAT'S YOUR DEFENDANTS, YOU WOULD BE STUCK WITH OUTSIDE EXPERTS. YOU WOULD BE STUCK WITH PEOPLE GETTING CHALLENGES BECAUSE THEY WERE UNQUALIFIED. IT WOULD NOT TAKE MUCH FOR THE DEFENDANTS HERE IN THE PHARMACEUTICAL INDUSTRY TO TAKE THE WHOLE FIELD OF POTENTIAL EXPERTS AND GET RID OF THEM ALL BY HAVING THEM COME IN ONCE A YEAR.

YOU KNOW, I THINK IT'S IMPORTANT HERE. THE

DEFENDANTS THEMSELVES, WHO ARE THE LARGE DRUG COMPANIES IN THE

WORLD, COULD NOT FIND ONE PERSON WITH EXPERIENCE IN DIABETES

REGULATION WHO WOULD SUPPORT THEIR PREEMPTION ARGUMENT. NOT

ONE. THEY HAD TO FIND AN EXPERT WHO DID SOME OTHER FIELD.

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WE	E FOUND ONE.	WE FOUND ONE WHO	O IS QUALIFIED. WE
FOUND THE PR	REEMINENT ONE	IN THE FIELD.	THEIR ARGUMENT HERE IS
WELL, WE CAN	N GET RID OF A	NY EXPERT WE WAN	NT. WE CAN GET RID OF
ANY FORMER I	FDA OFFICIAL I	F WE RETAIN THEN	M ONCE FOR A CONSULTING
AGREEMENT.	THAT IS THE E	XACT OPPOSITE OF	F ALL THE PRECEDENT.

THE PRECEDENT IS VERY CLEAR. THE COURT IS SUPPOSED TO CONSIDER THE POLICY IMPLICATIONS. IT'S SUPPOSED TO CONSIDER THE EFFECT ON EXPERTS. IT'S SUPPOSED TO CONSIDER THE EFFECT ON OTHER LITIGATIONS.

IF WE SET UP, WITHOUT ANY PRECEDENT, A NEW RULE OF ANYONE WHO HAS EVER CONSULTED FOR THE DEFENDANT IS OUT OF THE BOX, THEY KNOW EXACTLY WHAT THEY'LL DO. EVERY PERSON WHO LEAVES THE FDA IS GOING TO GET THEIR ONE DAY AT AN ADVISORY PANEL AND THEN THEY'LL BE GONE.

AND I THINK IN THIS TYPE OF CASE, PARTICULARLY SINCE
WE HAVE NOTHING SPECIFIC -- THE ACTUAL STANDARD HERE ARE
SPECIFIC AND UNAMBIGUOUS DISCLOSURES THAT IF REVEALED WOULD
PREJUDICE THE PARTY.

AND IT'S STRANGE HERE. WE HAVE NO IN-CAMERA
SUBMISSIONS. WE HAVE NO TESTIMONY. WE HAVE NO DECLARATIONS
WHATSOEVER. THERE IS NO BASIS TO ACTUALLY, FACTUALLY FIND
SOMETHING LIKE THAT.

YOU KNOW, THEIR BRIEF REFERENCES ALLEN MOSES. THEIR BRIEF REFERENCES MICHELLE THOMPSON. WHERE ARE THEY? WHERE ARE THEIR DECLARATIONS? WHERE IS ALLEN MOSES WITH A DECLARATION TO

YOUR HONOR, IN CAMERA, I TOLD ALEXANDER FLEMING X? AND IF
ALEXANDER FLEMING REVEALS X TO THE PLAINTIFFS, THIS WILL BE
PREJUDICIAL IN THE CASE. THERE IS NOT ONE EXAMPLE OF THAT.

THEIR OWN BRIEF DEPENDS ENTIRELY ON DOCUMENTS ALREADY IN DISCOVERY. THAT'S NOT SOMETHING THAT IF REVEALED WOULD PREJUDICE THE PARTY. THAT'S SOMETHING THE PARTY IS SUPPOSED TO HAVE AND SUPPOSED TO LOOK AT.

SO I AM GETTING A LITTLE AFIELD FROM YOUR QUESTION.

THE COURT: IT'S ALL APPRECIATED. AND I DON'T WANT
YOU TO GET THE FEELING THAT I THINK INSIDER STATUS SOMEHOW
WOULD EQUATE TO A ONE-TIME CONSULT MEANS THEY ARE DISQUALIFIED.
I THINK THE INSIDER-STATUS-TYPE ARGUMENT REALLY IS MORE IN THE
PRONG OF PREJUDICE AS A RESULT OF WHAT RELEVANT INFORMATION IF,
IN FACT, SOME WAS, WOULD THEN PRODUCE.

SO I'M LOOKING AT IT VERY NARROWLY, AND I JUST DON'T WANT YOU TO FEEL LIKE I AM SOMEHOW EXPANDING THE LAW. WE ARE USING IT CATEGORICALLY AS AN ARGUMENT -- OR I THINK MR. BROWN DID -- AND I THINK IT HAS SOME --

MR. KENNERLY: IF I MAY, YOUR HONOR.

THE COURT: -- SOME PIZZAZ IN TERMS OF PREJUDICE.

MR. KENNERLY: IF I MAY, YOUR HONOR, THEN THE PREJUDICE TO US IS EVEN GREATER BECAUSE WHO AM I GOING TO CALL? WHOEVER I CALL, AFTER THIS, ONCE THEY'VE KNOCKED EVERYONE OUT OF THE BOX, THE FIRST THING THEY ARE GOING TO SAY IS YOU'VE NEVER TESTIFIED FOR A DRUG COMPANY, HAVE YOU? AND YOU NEVER

1	WORKED IN A DRUG COMPANY, DID YOU? WHATEVER EXPERT WE HAVE, IF
2	THEY ARE ALLOWED TO HAVE SOMETHING LIKE THIS IF IT'S
3	PREJUDICIAL TO THEM FOR US TO HAVE SOMEONE THAT FORMERLY WORKED
4	FOR THEM, IT WILL BE PREJUDICIAL FOR US TO BE FORCED TO TAKE AN
5	EXPERT FROM A COMPLETELY DIFFERENT FIELD OR SOMEONE WITH NO
6	PHARMACEUTICAL INDUSTRY EXPERIENCE.
7	THE COURT: WELL, IT WOULD DEPEND. I MEAN, IF THE
8	FORMER EXPERT CONSULTED WITH THEM AND HAD SOME RELATIONSHIP TO
9	VICTOZA OR SOME OF THE OTHER DRUGS OF THE OTHER DEFENDANTS.
10	BUT THAT IS THE EXTREME. HERE, ONE COULD SAY WHAT ABOUT
11	DR. MICHAEL HAMRELL, THE JCCP PREEMPTION EXPERT?
12	MR. KENNERLY: WELL, YOUR HONOR, POSSIBILITY.
13	CERTAINLY, STANDING HERE TODAY, I WOULD SAY THE JCCP EXPERT IS
14	ALSO EQUALLY ONE OF THE BEST IN THE FIELD. BUT AT THE SAME
15	TIME ALL OF THIS GOES BACK TO THIS IS A TOUGH FIELD TO FIND
16	ANYBODY IN. THEY HAVE REPEATEDLY REFERENCED THE PELLERIN CASE.
17	THE PELLERIN CASE GRANTED DISQUALIFICATION BECAUSE
18	THE REPORTER: COUNSEL, COULD YOU PLEASE SLOW DOWN.
19	MR. KENNERLY: THE EXPERT WAS NOTHING SPECIAL.
20	I'M SORRY. P-E-L-L-E-R-I-N.
21	THE COURT: AND SLOWER, TOO.
22	SO IN PELLERIN THEY GRANTED DISQUALIFICATION
22 23	SO IN PELLERIN THEY GRANTED DISQUALIFICATION BECAUSE AND I DIDN'T HEAR THE ENDING.

ARGUMENT BY THE PLAINTIFF THAT THE EXPERT WAS ANYTHING OTHER

1	THAN NORMAL. THE COURT FOUND YOU CAN GO OUT AND GET ANYONE
2	ELSE TO FILL THIS ROLE. WHEN WE'RE TALKING ABOUT HOW THE FDA
3	WOULD RESPOND TO A CBE ON A DIABETES MEDICATION, WELL, THEN,
4	YOU'RE TALKING ABOUT A MUCH MORE NARROW FIELD THERE OF PEOPLE
5	WHO ARE POTENTIALLY QUALIFIED.
6	AND WHENEVER THERE ARE PLAINTIFFS' EXPERTS IN THESE
7	TYPES OF PHARMACEUTICAL CASES, THE DEFENDANT ALWAYS TRIES TO
8	MOVE TO PRECLUDE THEM, ALWAYS SAYS THEY ARE UNQUALIFIED FOR
9	EVERYTHING THAT THEY HAVE.
10	WE HAVE, HERE, THE PREEMINENT EXPERT IN THE FIELD,
11	SOMEONE WHO IS UNDENIABLY ABLE TO COMMENT ON ALL OF THESE
12	ISSUES. SO THE IDEA THAT WELL, IT'S PREJUDICIAL TO THEM
13	BECAUSE HE HAS EXPERIENCE IN THE DRUG INDUSTRY, NO. THAT'S
14	BENEFICIAL FOR THE COURT. IT'S BENEFICIAL FOR THE
15	FACT-FINDERS. HE KNOWS HOW THIS WORKS. HE KNOWS HOW THIS
16	SHOULD WORK.
17	THE COURT: OKAY. I THINK THE ARGUMENT IS A LITTLE
18	MORE DEEPER THAN YOU CHARACTERIZE, BUT I UNDERSTAND YOUR
19	POINT, CERTAINLY.
20	SO ANYTHING ELSE YOU WANT TO ADD, MR. KENNERLY?
21	MR. KENNERLY: NOT ON THIS POINT, YOUR HONOR.
22	THE COURT: SO, MR. BROWN, YOU WANT TO RESPOND AT ALL
23	OR DO YOU GIVE UP?
24	MR. BROWN: THANK YOU.

(LAUGHTER)

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1	THE COURT:	Τ	GUESS	YOU	DON 'T	GIVE	UP.

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MR. BROWN: THANK YOU. FIRSTLY, I WILL ADDRESS THIS IDEA THAT THERE IS NO PRECEDENT. THERE IS PRECEDENT,

SPECIFICALLY IN CALIFORNIA, WE THINK, THAT'S ANALOGOUS TO THIS CASE.

THE PELLERIN CASE, AS WAS MENTIONED, THAT'S A FORMER EMPLOYEE WHO SIGNED MULTIPLE CONFIDENTIALITY AGREEMENTS.

THAT'S IN THIS DISTRICT, 2012.

THE ORACLE CASE, IN THE NORTHERN DISTRICT IN 2012,
THAT WAS A FORMER CONSULTANT, LIKE DR. FLEMING, WHO SIGNED
MULTIPLE AGREEMENTS.

A THIRD CASE IN CALIFORNIA IS THE *ADVENTISTS* CASE, WHICH WAS IN THE CENTRAL DISTRICT IN 2005. AGAIN, THAT WAS A FORMER CONSULTANT IN THE CASE.

IN ALL OF THOSE CASES YOU HAD FORMER EMPLOYEES OR CONSULTANTS HERE IN CALIFORNIA WHO WERE DISQUALIFIED FROM TESTIFYING.

SECOND, THIS IDEA THAT HE'S SPECIAL AND THEY CAN'T FIND ANOTHER EXPERT. WHAT MAKES HIM SPECIAL IN OUR JUDGMENT IS THAT HE HAD ACCESS TO INFORMATION THAT HE ONLY GOT THROUGH THE BREACH OF CONFIDENTIALITY AGREEMENTS.

HOWEVER, WE WILL ACKNOWLEDGE THAT DR. FLEMING DOES HAVE SPECIALIZED KNOWLEDGE RELATING TO HOW THE FDA WORKS, RELATING TO HOW HIS FORMER DIVISION WORKS, RELATED TO FDA POLICIES, REGULATIONS AND PROCEDURES.

IF WE JUST HAD A REPORT THAT SPOKE TO THOSE ISSUES,

IT WOULD BE A COMPLETELY DIFFERENT KETTLE OF FISH, BUT WE

DON'T. WHEN HE CROSSES OVER INTO ENDOCRINOLOGY AND INTO THE

INTERWORKINGS AND DATA OF OUR CLIENT, IT'S A DIFFERENT STORY.

FIRST, THERE ARE MANY DIFFERENT ENDOCRINOLOGISTS THAT
THE PLAINTIFFS CAN PICK ALL ACROSS THE COUNTRY. THEY DON'T
NEED DR. FLEMING ON THAT ISSUE OR ON CAUSATION. YOU HAVE TO
REMEMBER HE IS A DIABETOLOGIST OR ENDOCRINOLOGIST, AND WE'RE
TALKING ABOUT A CANCER ISSUE. WE KNOW THAT PLAINTIFFS HAVE
OTHER OPTIONS BECAUSE THEY HAVE ALREADY DISCLOSED OTHER EXPERTS
IN THIS CASE. FIVE OF THEM. AND MOST OF THOSE OTHER PEOPLE
HAVE MORE SPECIALIZED KNOWLEDGE RELATED TO THE CAUSATION AND
CANCER ISSUES THAN DR. FLEMING.

THEY HAVE IDENTIFIED A MOLECULAR BIOLOGIST. THEY
HAVE IDENTIFIED A PATHOLOGIST. AND THEY HAVE IDENTIFIED AN
ONCOLOGIST. ALL OF WHOM, IF PLAINTIFFS WISH, CAN HAVE THEM
ISSUE REPORTS AND SPEAK TO THE CAUSATION ISSUE. AND AS BEST I
CAN TELL, NONE OF THOSE EXPERTS HAD CONFIDENTIALITY AGREEMENTS
WITH OUR CLIENTS. SO THEY DO HAVE OTHER OPTIONS.

THE THIRD ISSUE -- AND THIS KIND OF GETS INTO A SLOG.

AND I'M NOT GOING TO GO THERE, UNLESS YOU THINK IT WILL BE

HELPFUL, YOUR HONOR. BUT I CAN GO BLOW-BY-BLOW THROUGH THESE

DOCUMENTS AND SHOW EXACTLY THE KIND OF INFORMATION THAT

DR. FLEMING WAS EXPOSED TO AND IDENTIFY EACH AND EVERY EXHIBIT.

BUT FROM A BIG-PICTURE PERSPECTIVE, I WOULD LOOK

BEYOND WHAT HE CALLS THE NOTEBOOK THAT WAS GIVEN TO HIM BEFORE

THESE MEETINGS. IT'S NOT JUST WHAT WAS GIVEN TO HIM BEFORE

THESE MEETINGS. IF YOU LOOK AT THE AGENDAS FOR EVERY ONE OF

THESE MEETINGS, THERE ARE PRESENTATIONS FROM NOVO PEOPLE AT

EVERY ONE OF THEM, WHERE THEY'RE DISCLOSING THEIR THOUGHTS,

THEIR DECISION-MAKING PROCESSES, THEIR INTERPRETATION OF DATA,

THEIR REGULATORY STRATEGIES, THEIR LABEL.

THEY ARE ALSO ASKING OTHER PEOPLE TO GIVE THEM

CONFIDENTIAL ADVICE. AND DR. FLEMING IS HEARING ALL OF THAT.

THROUGHOUT THE EXHIBITS, I CAN NAME EVERY ONE OF THEM.

YOU HAVE REFERENCES TO MANY DIFFERENT PIECES OF
INFORMATION THAT HE RECEIVED, GOING ALL THE WAY BACK TO 2000.
IN EXHIBIT 10, YOU HAVE DRAFTS, SYNOPSES, LECTURES BY BOARD
MEMBERS, PRESENTATIONS FOR PLANS OF THE CLINICAL PROGRAM. I'LL
LIST ALL THE EXHIBITS JUST SO WE HAVE IT IN THE RECORD.

THE COURT: OKAY.

MR. BROWN: EXHIBITS 10, 11, 12, 13, 15, 16, 18, 23, AND 24. YOU WILL SEE COUNTLESS REFERENCES TO INFORMATION, INSIGHTS, THOUGHTS THAT WERE COMMUNICATED TO DR. FLEMING AND OTHERS. THERE IS NO QUESTION THAT CONFIDENTIAL INFORMATION WAS EXCHANGED.

HE WAS ALSO ON TELECOMS, WHERE HE IS TALKING ABOUT FAST-TRACK APPROVAL AND LOOKING AT DRAFT APPLICATIONS FOR THE APPROVAL OF VICTOZA.

AGAIN, YOU'RE GOING TO HAVE THE PLAINTIFFS IN THIS

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CASE SON	MEHOV	V CRI	ITICI	ZINC	F THAT	THES	SE D	RUGS	WERE	E RU	JSHEI	) [	ΓΟ	
MARKET,	AND	YOU	HAVE	A E	PERSON	WHO	IS	INVOI	LVED	DII	RECTI	ĹΥ	WITH	THE
APPLICA:	TION	ITSE	ELF.	JOY	J WILL	SEE	THA	T IN	ALL	OF	THE	ΕΣ	XHIBIT	S.

I ALSO WANTED TO POINT OUT -- JUST GOING TO THIS NO EVIDENCE OF PANCREATIC CANCER. WE CERTAINLY CONTEND THERE IS NO EVIDENCE THAT THESE DRUGS ARE LINKED TO PANCREATIC CANCER.

BUT THIS BETA CELL REGENERATION ISSUE IS A SIGNIFICANT ONE. THE JULY 24TH, 2003 CONFIDENTIALITY AGREEMENT IS SPECIFICALLY RELATED TO THE REGENERATION OF BETA CELLS, WHICH IS THE PLAINTIFFS' THEORY OF THE CASE.

AND IF YOU LOOK AT EXHIBIT 12 -- WELL, I GAVE YOU THE EXHIBITS BEFORE. BUT IN EXHIBIT 12, YOU'VE GOT A SPECIFIC QUESTION BEING ASKED: WHAT ARE THE SAFETY CONCERNS FOR THIS PRODUCT?

AND THERE IS ONE REFERENCE TO A CONDITION CALLED NESIDIOBLASTOSIS, WHICH IS A RARE PANCREATIC CANCER. IT'S RAISED. WE CERTAINLY DON'T BELIEVE THAT IT MEANS ANYTHING IN TERMS OF A LINK BETWEEN THESE DRUGS AND PANCREATIC CANCER, BUT THERE IS A REFERENCE TO IT. AND I SAID THERE IS MULTIPLE REFERENCES TO THE ISSUE OF PANCREATITIS, TO THE EFFECTS THAT THESE INCRETINS HAVE ON BETA CELLS, AND TO STUDIES WHICH DR. FLEMING IS CRITICIZING. SO I THINK WE'VE GOT A LOT OF INFORMATION IN THE DOCUMENTS THEMSELVES THAT ARE CONTEMPORANEOUS.

THE OTHER THING I WANT TO POINT OUT -- BECAUSE THIS

IDEA THAT WE NEED AN AFFIDAVIT TO PROVE SOMETHING WHEN WE HAVE
THE DOCUMENTS JUST ISN'T TRUE. BUT THERE IS ONE EXHIBIT IN
PARTICULAR THAT I THINK IS INTERESTING. AND IT'S A
CONTEMPORANEOUS DOCUMENT BY THE PERSON THAT MR. KENNERLY SAID
HE DEPOSED, MICHELLE THOMPSON.

EXHIBIT 23 IS AN E-MAIL FROM HER, WHERE SHE IS

SPECIFICALLY RAISING CONCERNS ABOUT PROPRIETARY INFORMATION

BEING GIVEN OUT TO THESE CONSULTANTS, AND SINGLING OUT

DR. FLEMING IN PARTICULAR. THAT'S EXHIBIT 23. AND I WILL GIVE

YOU THE DATE OF THAT DOCUMENT, AS WELL. IT'S OCTOBER 2004.

THE COURT: OKAY. NOW, MR. KENNERLY MADE SOME

REFERENCE TO WHERE IS THE BREACH, AND DOVETAILED THAT INTO THE

FACT THAT THESE AGREEMENTS SUNSET FOR A PERIOD, PERHAPS A YEAR

OR SO AFTER THEIR SIGNING. DOESN'T THAT UNDERCUT YOUR WHOLE

ARGUMENT, IN ESSENCE? IF THE AGREEMENTS SUNSET, THEN HOW COULD

THERE LATER BE BREACH?

MR. BROWN: I DON'T BELIEVE THAT'S TRUE WITH RESPECT TO ALL OF THESE AGREEMENTS, YOUR HONOR. I WOULD HAVE TO LOOK MORE CAREFULLY AT THAT. BUT THIS SUNSET IDEA IS THE FIRST TIME I'VE HEARD OF INFORMATION THAT HE IS ALLOWED TO DISCLOSE AFTER SOME PERIOD OF TIME. I'D LIKE TO LOOK CAREFULLY THROUGH THOSE SEVEN AGREEMENTS, BUT THAT'S NEWS TO ME.

THE COURT: FIRST TIME I HEARD IT, TOO. THAT IS WHY
I'M ASKING YOU. I CAN GO THROUGH THEM, AS WELL.

OKAY. SO ANYTHING ELSE YOU WANT TO ADD? LET'S SEE

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IF I HAVE ANY OTHER QUESTIONS WHILE I HAVE YOU AT THE PODIUM.

I THINK WE COVERED A GREAT DEAL OF ISSUES I WANTED TO NAIL

DOWN.

MR. BROWN: THE ONLY OTHER THING I WOULD POINT OUT,
YOUR HONOR, IS THE DEFENSE SHOULDN'T BE IN THE POSITION OF
HAVING TO PARSE WHAT COMES FROM DISCOVERY VERSUS WHAT COMES
FROM THIS CONFIDENTIAL RELATIONSHIP. THE PELLERIN CASE MAKES
REFERENCE TO THE INABILITY TO PARSE KNOWLEDGE AND THE FACT THAT
THE HUMAN BRAIN DOESN'T COMPARTMENTALIZE INFORMATION THIS WAY.

THE ADVENTISTS CASE ALSO RECOGNIZES THAT AN EXPERT MAY BE SUBCONSCIOUSLY INFLUENCED BY INFORMATION OBTAINED DURING A CONFIDENTIAL RELATIONSHIP. SO WE SHOULDN'T BE IN A POSITION OF HAVING TO PARSE WHAT MIGHT HAVE COME FROM DISCOVERY VERSUS WHAT MIGHT HAVE COME FROM THIS DECADE-LONG CONFIDENTIAL RELATIONSHIP.

THE COURT: YET YOU ARE ABLE TO, IT SOUNDS LIKE, TO ARTICULATE, CATEGORICALLY, AREAS THAT WOULD BE OF NO CONCERN VERSUS AREAS OF GREAT CONCERN, WHICH YOU DID EARLIER.

MR. BROWN: YES. MY COLLEAGUES AND I TALKED ABOUT

THIS BEFORE THE ARGUMENT. CERTAINLY, WE WOULD LIKE TO CONSIDER

WHATEVER THE PROFFER IS SO WE COULD SEE WHAT A REPORT LOOKS

LIKE THAT DOESN'T TOUCH ON THE ISSUES THAT WE'RE CONCERNED

ABOUT.

BUT WE CERTAINLY WOULD BE OPEN-MINDED TO A REPORT

THAT ONLY TALKED ABOUT FDA REGULATIONS, WHAT'S HAPPENING INSIDE

1	THE AGENCY, PERHAPS HOW THE AGENCY LOOKS AT ISSUES LIKE THIS.
2	BUT ONCE YOU START GETTING INTO CAUSATION-RELATED
3	ISSUES AND FACTS RELATED TO OUR CLIENT AND APPLYING ANY OF THAT
4	TO NOVO NORDISK AND THE DEVELOPMENT OF THIS PRODUCT, WE BELIEVE
5	THAT YOU START TO RUN INTO SIGNIFICANT PROBLEMS.
6	THE COURT: OKAY. WELL, THANK YOU. THANK YOU.
7	MR. THOMPSON, (SIC) DID YOU WANT TO RESPOND TO THAT
8	OR ADD SOMETHING FURTHER ON YOUR SIDE OF THAT?
9	MR. JOHNSON: I DID, YOUR HONOR. AND AGAIN, MIKE
10	JOHNSON.
11	THE COURT: I'M SORRY. I JUST HEARD MICHELLE
12	THOMPSON SO I CHANGED YOUR NAME.
13	MR. JOHNSON: NOT A PROBLEM, YOUR HONOR. BOTH OF
14	THEM FAIRLY COMMON.
15	I JUST WANTED TO BRIEFLY ADDRESS THE ISSUE OF WHETHER
16	OR NOT THESE CONFIDENTIALITY AGREEMENTS HAVE SUNSETTED. AND,
17	QUITE FRANKLY, I DON'T THINK THAT WE EXPECTED THIS TO BE AN
18	ISSUE TODAY BECAUSE THE AGREEMENTS THEMSELVES ARE VERY CLEAR.
19	SO, FOR EXAMPLE, IF YOU LOOK AT EXHIBIT NUMBER 2, IT
20	IS THE FIRST CONFIDENTIALITY AGREEMENT. AND IT IS SIGNED
21	SEPTEMBER 4TH OF 1999. AND ON THE SECOND PAGE OF THAT
22	EXHIBIT AND THIS IS UNDER THE SECTION ENTITLED
23	"CONFIDENTIALITY" IT SAYS: RECIPIENT UNDERTAKES FROM THE
24	DATE OF DISCLOSURE TO TREAT ALL RECEIVED INFORMATION AS
25	STRICTLY CONFIDENTIAL FOR A PERIOD OF FIVE YEARS FROM THE DATE

1	OF DISCLOSURE. AND, THEREFORE, NOT TO DISCLOSE IT TO ANY THIRD
2	PARTY WITHOUT THE PRIOR WRITTEN AND EXPRESS CONSENT OF NOVO,
3	AND TO MAKE NO USE OF IT EXCEPT AS SPECIFICALLY PROVIDED FOR IN
4	ARTICLE IV, WITHOUT THE PRIOR WRITTEN AND EXPRESS CONSENT OF
5	NOVO IN EACH CASE.
6	SO IN THAT FIRST AGREEMENT WE LOOK AT IT HAS A SUNSET
7	PROVISION, YOUR HONOR, OF FIVE YEARS.
8	WE THEN GO TO EXHIBIT NUMBER 3. THE DATE OF THE
9	FIRST ONE, AGAIN, YOUR HONOR, WAS SIGNED ON SEPTEMBER 4TH OF
10	1999.
11	SO WE GO TO THE SECOND ONE, WHICH IS EXHIBIT
12	NUMBER 3, AND THAT WAS SIGNED JANUARY 20TH OF 2000. AND, YOUR
13	HONOR, I'M NOT GOING TO READ ALL OF THESE, BUT I'M GOING TO
14	REPRESENT THAT THIS ONE ALSO HAS THE CONFIDENTIALITY SECTION.
15	AND IT IS LIMITED TO FIVE YEARS FROM THE DATE OF DISCLOSURE.
16	YOUR HONOR, WE THEN GO TO EXHIBIT NUMBER 4. AND
17	EXHIBIT NUMBER 4 IS THE THIRD CONFIDENTIALITY AGREEMENT. AND
18	IT HAS A SECTION I'M SORRY IT IS SIGNED MAY 9TH OF 2003.
19	AND IT HAS A SECTION CALLED "TERMINATION." AND IT SAYS: THIS
20	AGREEMENT SHALL COME INTO FORCE ON THE DATE OF THE LAST
21	SIGNATURE ADHERED TO AND SHALL REMAIN EFFECTIVE UNTIL FIVE
22	YEARS AFTER LAST SIGNING.

THIS ONE, AGAIN, HAS A SUNSET PROVISION OF FIVE YEARS.

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THE NEXT AGREEMENT, YOUR HONOR, IS EXHIBIT NUMBER 5,

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WHICH WOULD BE THE FOURTH CONFIDENTIALITY AGREEMENT. AND THAT
WAS ENTERED INTO ON JULY 3RD OF 2014. AND DR. FLEMING SIGNED
IT ON AND I'M SORRY. THAT IS 2003. AND DR. FLEMING SIGNED
IT, IT LOOKS LIKE, ON JULY 24TH OF 2003. AND THAT ONE HAS A
PROHIBITED ACT SECTION. AND THAT ONE SAYS: THE RECIPIENT
UNDERSTANDS AND AGREES THAT FOR A PERIOD OF FIVE YEARS FROM THE
RECEIPT OF ANY CONFIDENTIAL INFORMATION, SUCH CONFIDENTIAL
INFORMATION SHALL

AND YOUR HONOR, IT GOES ON FOR MULTIPLE PARAGRAPHS.

I'M NOT GOING TO READ THOSE INTO THE RECORD. BUT, AGAIN, THE

POINT IS IS THAT IT HAS A SUNSET PROVISION OF FIVE YEARS.

YOUR HONOR, EXHIBIT NUMBER 6 WOULD BE THE FIFTH CONFIDENTIALITY AGREEMENT. THAT WAS EXECUTED ON SEPTEMBER 26TH OF 2003. THAT ALSO HAS A TERMINATION AGREEMENT THAT SUNSETS AFTER FIVE YEARS.

YOUR HONOR, THE NEXT AGREEMENT IS EXECUTED ON DECEMBER 20TH OF 2007. AND THIS ONE SAYS: THE AGREEMENT SHALL COMMENCE AND HAVE A TERM OF ONE YEAR, TO EXPIRE DECEMBER 31ST OF 2008.

AND THEN, YOUR HONOR, THE FINAL ONE, WHICH IS AN ADDENDUM TO A HEALTHCARE PROFESSIONAL CONSULTING AGREEMENT -- WHICH I'M NOT POSITIVE, BUT I THINK WAS THE PRECEDING ONE, WHICH I BELIEVE WOULD BE THE SEVENTH AGREEMENT THAT COUNSEL REFERRED TO -- THAT WAS EXECUTED ON OCTOBER 9TH OF 2008. AND THAT ONE, AGAIN, REFERRED BACK TO THE PRIOR ONE, WHICH HAD AN

AGREEMENT OF ONE YEAR. AND IT SAYS: EXCEPT AS OTHERWISE PROVIDED HEREIN ALL TERMS AND CONDITIONS OF THE CONSULTING AGREEMENT REMAIN IN FULL FORCE AND EFFECT.

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SO REGARDLESS, EVEN IF IT WENT BACK TO ONE OF THE FIVE-YEAR ONES, IT WOULD STILL HAVE SUNSETTED BEFORE DR. FLEMING'S INVOLVEMENT IN THIS CASE.

YOUR HONOR, I DON'T KNOW IF MR. KENNERLY HAD ANYTHING ADDITIONAL TO ADD, BUT I JUST WANTED TO CLARIFY, FOR THE RECORD, THE STATUS OF THE CONFIDENTIALITY AGREEMENTS FROM THE PLAINTIFFS' PERSPECTIVE.

THE COURT: THANK YOU. I APPRECIATE THAT.

MR. KENNERLY, DO YOU HAVE ANYTHING TO ADD?

MR. KENNERLY: IF I MAY, YOUR HONOR. WHAT I WANTED
TO GET TO WAS THE WAY THAT MR. BROWN DESCRIBED IT OF HE DIDN'T
THINK THAT THEY SHOULD HAVE TO PARSE THROUGH TO FIND WHAT MIGHT
PREJUDICE THEM DOWN THE LINE.

NOW, FIRST, JURORS EVERY DAY ARE ASKED TO PARSE
THROUGH TREMENDOUS AMOUNTS OF DETAILED INFORMATION TO DECIDE
THE QUESTIONS BEFORE THEM. THE CASE LAW HERE IS UNEQUIVOCAL.
IT IS A HEAVY BURDEN ON THE MOVING PARTY TO JUSTIFY THE EXTREME
SANCTION. THESE ARE COMMON TERMS IN THESE CASES OF
DISQUALIFICATION THROUGH SPECIFIC AND UNAMBIGUOUS DISCLOSURES.

I THINK THE CONCESSION THAT THEY CAN'T DO THIS, THAT INSTEAD IT'S SUPPOSED TO BE A GESTALT OF POTENTIAL KNOWLEDGE IS AN ADMISSION THAT THEY CANNOT MEET THE ACTUAL ELEMENTS OF HERE,

WHICH IS SPECIFIC INFORMATION ABOUT IT.

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THE IDEA THAT THEY COULD DO A BLOW-BY-BLOW THROUGH

THE EXHIBITS -- AS YOUR HONOR NOTED, THE EXHIBITS ARE ALL IN

DISCOVERY. HOW COULD YOU BE PREJUDICED BY CONFIDENTIAL

INFORMATION IN DISCOVERY?

AND AGAIN, MUCH OF WHAT THEY ARE REFERENCING -DR. FLEMING SAW AGENDA ITEMS, HE SAW PRESENTATIONS, HE WAS
THERE FOR DISCUSSIONS -- THAT IS IN THE MATERIALS DEFENDANTS
THEMSELVES ATTACHED.

THERE IS NO SPECIAL KNOWLEDGE IN THERE. AND EVEN IF
THERE WAS, IT'S PART OF THE DISCOVERY. SO THE IDEA, I GUESS,
IS DR. FLEMING HAD A CONVERSATION OUTSIDE, AT, LIKE, A
RESTAURANT, WITH SOMEONE ELSE THERE AND SUDDENLY LEARNED
SOMETHING THERE. THE IDEA THAT THAT INFORMATION IN DISCOVERY
IS SOMEHOW ALSO CONFIDENTIAL AND PRIVILEGED, I DON'T THINK CAN
CARRY THE DAY.

AND IF YOU LOOK AT THE CASES THEY ARE RELYING ON, WE DEAL WITH ORACLE AND ADVENTISTS ON PAGE SIX OF OUR BRIEF.

THERE ARE INTELLECTUAL PROPERTY CASES IN WHICH THE EXPERT WAS HEAVILY INVOLVED IN IT. THE ORACLE CASE, JUST TO NARROW DOWN ON ONE ISSUE ON IT, HAD A DECLARATION FROM THE COMPANY'S VP, VERY SPECIFICALLY DELINEATING EXACTLY WHAT THAT INDIVIDUAL KNEW, WHAT HE LEARNED, THAT HE HAD INFORMATION THAT HAD NOT BEEN SHARED WITH THE OTHER PARTY.

AND THAT WAS ONLY ONE ELEMENT OF WHAT THE COURT WENT

1	THROUGH IN ORDER TO FIND DISQUALIFICATION.	IT ALS	O FOUND	) IT	AS
2	A RESULT OF HIS CO-INVENTOR STATUS.				
3	SO AGAIN, THE DEFENDANTS' ARGUMENT	S HERE	ARE JU	JST	TOO

SO AGAIN, THE DEFENDANTS' ARGUMENTS HERE ARE JUST TOO
FAR OFF OF THE EXISTING CASE LAW AND WHAT IS THEIR BURDEN TO
PROVE. THEY DO HAVE TO PARSE THROUGH IT. AND THEY MUST SHOW
YOUR HONOR WHAT SPECIFIC AND UNAMBIGUOUS DISCLOSURES, IF
REVEALED TO US, WOULD PREJUDICE THEM.

AND THAT'S IT ON THOSE POINTS.

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THE COURT: AND ANYONE ELSE ON THE PLAINTIFFS' TEAM WANT TO ADD ANYTHING BEFORE I TURN TO THE DEFENSE, GENERALLY, AND GIVE THEM ALL A CHANCE, TOO?

MR. SHKOLNIK: NO, YOUR HONOR.

THE COURT: IT SEEMS LIKE NOT.

MR. BROWN, ANYTHING FURTHER YOU WOULD LIKE TO ADD ON NOVO'S BEHALF?

MR. BROWN: JUST BRIEFLY, YOUR HONOR. FIRSTLY, IT'S

A BIT UNFAIR TO BE RESPONDING TO THIS SUNSET ARGUMENT FOR THE

FIRST TIME IN AN ORAL ARGUMENT.

THE COURT: I UNDERSTAND.

MR. BROWN: THIS WAS NEVER MENTIONED, NOT A WORD OF IT, IN THE BRIEFING. AND WE CERTAINLY WOULD HAVE BEEN ABLE TO ADDRESS THIS IN GREAT DETAIL HAD WE HAD AN OPPORTUNITY TO RESPOND, A FAIR OPPORTUNITY TO RESPOND.

WITH THAT SAID, JUST GOING THROUGH SOME OF THE THESE AGREEMENTS VERY QUICKLY. AND THIS IS NOT GOING TO BE A

COMPREHENSIVE JOB, BUT JUST TO GIVE YOU AN EXAMPLE OF WHAT WE'RE TALKING ABOUT.

IF YOU LOOK AT THE JUNE 2003 AGREEMENT, AND YOU GO TO ARTICLE II, WHICH IS CONFIDENTIALITY, SECTION 2.1, YOU WILL SEE THAT THE INTENT IS TO MAKE ALL OF THIS INFORMATION STRICTLY CONFIDENTIAL DURING THE TERM OF THIS AGREEMENT AND THEREAFTER. THAT'S ONE THAT I LOOKED AT.

THE COURT: IS THAT EXHIBIT 4?

MR. BROWN: I DON'T HAVE THE EXHIBIT NUMBER ON THAT ONE, BUT IT'S THE JUNE 11, 2003 AGREEMENT.

THE COURT: OKAY.

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MR. BROWN: AND THEN IF YOU LOOK AT, AGAIN, THE
JUNE 25, 2007 AGREEMENT, IT'S THE SAME LANGUAGE: TO TREAT ALL
INFORMATION STRICTLY CONFIDENTIAL DURING THE TERM OF THIS
AGREEMENT AND THEREAFTER.

IF YOU LOOK AT THE AGREEMENT DATED DECEMBER 20, 2007, FOR EXAMPLE, THERE IS NO SUNSET RELATED TO CONFIDENTIAL INFORMATION: CONSULTANT UNDERSTANDS AND AGREES THAT CONFIDENTIAL INFORMATION SHALL AT ALL TIMES REMAIN THE SOLE PROPERTY OF NOVO NORDISK.

THIS IS SOMETHING THAT WE'D CERTAINLY BE HAPPY TO BRIEF FURTHER, IF GIVEN THE OPPORTUNITY, IF THIS IS SOMETHING THAT IS OF INTEREST TO YOUR HONOR.

THE COURT: OKAY. WELL, THANK YOU. LET ME THINK ABOUT THAT.

AND I KNOW THE OTHER DEFENDANTS JOIN IN THE MOTION.

IS THERE ANYTHING ANY OF THEM WOULD LIKE TO SAY ON ANY OF THE

ISSUES WE'VE DISCUSSED, ISSUES WE HAVEN'T DISCUSSED, OR STILL

THINGS WE WILL BE FOCUSING ON IN THE RULING?

YES, SIR.

MR. BOEHM: YOUR HONOR, PAUL BOEHM REPRESENTING

MERCK. ALTHOUGH PLAINTIFFS FILED ONLY ONE OPPOSITION BRIEF

BEFORE THE COURT THIS AFTERNOON, THERE ARE ACTUALLY TWO

DISTINCT AND SEPARATE MOTIONS TO DISQUALIFY DR. FLEMING. IF

THE COURT HAS QUESTIONS OR WISHES TO HEAR ARGUMENT ABOUT THE

SECOND OF THOSE MOTIONS, WHICH CONCERNS THE ISSUE OF

CONFIDENTIAL MATERIAL THAT WAS PROVIDED BY PLAINTIFFS' COUNSEL

TO DR. FLEMING CONTRARY TO THE TERMS OF THE PROTECTIVE ORDER,

THEN WE WOULD BE HAPPY TO ADDRESS THAT MOTION, AS WELL.

THE COURT: YOU KNOW, I HAVE THAT ONE FAIRLY WELL IN MIND, ALTHOUGH THE TWO ARE SO INTIMATELY CONNECTED, IT'S PROBABLY NOT A FAIR STATEMENT. IF THERE IS ANYTHING YOU WANT TO STRESS OR POINT OUT, I WILL GIVE YOU THAT OPPORTUNITY, BUT I DON'T HAVE ANY SPECIFIC QUESTIONS.

SHORT OF STRIKING THE REPORT, WHAT OTHER SANCTION
WOULD BE APPROPRIATE FOR A VIOLATION OF THE PROTECTIVE ORDER
HERE? AND I SAY THAT IN THE CONTEXT OF STRIKING THE REPORT
BEING A VERY DRASTIC REMEDY, WITH THE COURTS TENDING TO WANT TO
LOOK FOR OTHER VIABLE AND PERHAPS NOT AS DRASTIC APPROACHES TO
THINGS LIKE SANCTIONS. I MEAN, WHAT ELSE COULD WE DO?

1	MR. BOEHM: YES, YOUR HONOR. FIRST, IF I COULD
2	ADDRESS THE IMPORTANT DISTINCTIONS BETWEEN THE TWO MOTIONS.
3	THE COURT: OF COURSE.
4	MR. BOEHM: NOVO'S MOTION, AS YOU JUST HEARD,
5	CONCERNS CONFIDENTIAL INFORMATION THAT NOVO PROVIDED TO
6	DR. FLEMING OVER THE COURSE OF MANY YEARS.
7	THE SECOND MOTION BEFORE THE COURT TODAY CONCERNS
8	CONFIDENTIAL INFORMATION THAT PLAINTIFFS PROVIDED TO
9	DR. FLEMING DOCUMENTS THAT COUNSEL PROVIDED TO DR. FLEMING
10	UNDER THE TERMS OF THE PROTECTIVE ORDER.
11	WITH RESPECT TO THE VIOLATION THAT WE BELIEVE
12	OCCURRED WHEN PLAINTIFFS' COUNSEL PROVIDED THOSE CONFIDENTIAL
13	DOCUMENTS TO DR. FLEMING WITHOUT PROVIDING ADVANCE NOTICE TO
14	DEFENDANTS PURSUANT TO THE TERMS OF THE PROTECTIVE ORDER, THE
15	COURT HAS BEFORE IT A RANGE OF POSSIBLE REMEDIES AND BROAD
16	DISCRETION IN DECIDING WHICH OF THOSE REMEDIES ARE
17	PROPORTIONATE AND APPROPRIATE.
18	WHEN YOU LOOK AT THE CASE LAW, COURTS CONSIDER
19	POSSIBLE SANCTIONS, INCLUDING MONETARY SANCTIONS,
20	DISQUALIFICATION; AND, INDEED, IN SOME CASES, DISQUALIFICATION
21	WITHOUT LEAVE TO REPLACE THE DISQUALIFIED EXPERT.
22	WE'VE REQUESTED IN THIS CASE THAT DR. FLEMING BE
23	DISQUALIFIED AS THE APPROPRIATE AND PROPORTIONATE REMEDY
24	BECAUSE ALTHOUGH IT DOESN'T MAKE DEFENDANTS ENTIRELY WHOLE, IT
25	DOES RELIEVE DEFENDANTS OF THE IMPOSSIBLE POSITION THAT THEY

1	OTHERWISE WOULD BE PLACED IN IF DR. FLEMING WERE NOT
2	DISQUALIFIED.
3	IT WOULD BE PARTICULARLY IN LIGHT OF THE FACT THAT
4	PLAINTIFFS HAVE BEEN TELLING US, AND HAVE NOW INFORMED THE
5	COURT, THAT THEY INTEND TO DESIGNATE DR. FLEMING AS THE GENERAL
6	CAUSATION EXPERT, IT WOULD BE VERY DIFFICULT, IF NOT
7	IMPOSSIBLE SHOULD I PAUSE, YOUR HONOR?
8	(TELEPHONE INTERRUPTION)
9	THE COURT: YES. LET'S SEE.
10	IS THAT YOUR IPHONE, JEANNETTE?
11	THE REPORTER: NO. IT'S SOMEBODY ON THE PHONE.
12	THE COURT: BECAUSE YOU'RE ALWAYS LISTENING TO MUSIC,
13	I FIGURE YOU'RE SIMILARLY DOING IT HERE. JUST KIDDING.
14	(LAUGHTER)
15	THE REPORTER: NO, IT'S SOMEONE ON THE PHONE.
16	THE COURT: IT'S SOMEONE ON THE PHONE. IF ANYONE IS
17	ON THE PHONE, HAVING ANY SEPARATE CONVERSATIONS, PLEASE SUSPEND
18	IT FOR NOW. MAYBE EVERYBODY ON THE PHONE SHOULD PUT THEIR
19	PHONES ON MUTE SO WE CAN HEAR, AND MAYBE THAT WILL TAKE THIS
20	FEEDBACK OUT OF THIS.
21	(PAUSE)
22	WE MAY BE THERE.
23	MR. BOEHM: IT SOUNDS NICE.
24	THE COURT: GO AHEAD.
25	MR. BOEHM: YOUR HONOR, DR. FLEMING HAS SUBMITTED A

REPORT AND IT'S 108 PAGES LONG.

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THE COURT: I KNOW.

MR. BOEHM: AND IT TOUCHES ON A VARIETY OF ISSUES,

VIRTUALLY EVERY MEDICAL AND SCIENTIFIC ISSUE THAT'S CONCEIVABLY

TO BE ADDRESSED IN THE LITIGATION IN SOME FORM OR FASHION.

DEFENDANTS TO CROSS-EXAMINE DR. FLEMING ABOUT HIS OPINIONS AND THE MATERIALS THAT HE RELIES UPON IN HIS REPORT WITHOUT FOCUSING ADDITIONAL ATTENTION ON THE VERY CONFIDENTIAL DOCUMENTS THAT NEVER SHOULD HAVE BEEN PROVIDED TO HIM. AND POSSIBLY, IF THE CROSS-EXAMINATION IS TO BE FULSOME AND ROBUST — POSSIBLY NEEDING TO DIVULGE ADDITIONAL CONFIDENTIAL INFORMATION TO DR. FLEMING THAT HE HAS NOT YET EVEN SEEN.

NOW, IT'S COME UP TODAY THAT MAYBE THERE COULD BE AN ALTERNATIVE REMEDY. AND THAT IS ONE THAT WE SUGGESTED AS A POSSIBILITY, AS WELL, IN OUR BRIEFING. AND THAT IS THAT DR. FLEMING'S REPORT BE STRICKEN. IF YOU LOOK AT THAT 108-PAGE REPORT, APPROXIMATELY THREE TO FIVE PAGES OF IT ACTUALLY DEAL WITH THE ISSUE OF PREEMPTION. AND OVER 100 PAGES OF IT DEALS WITH GENERAL CAUSATION.

NOW, IF THAT'S THE REPORT WE WERE DEALING WITH, THE THREE-TO-FIVE-PAGE REPORT, WE WOULD BE IN A DIFFERENT POSITION, AS MR. BROWN NOTED. AND ALTHOUGH I DON'T KNOW THAT THE EQUITIES WOULD BE COMPLETELY SET IN EQUIPOISE, I THINK IT WOULD GO A LONG WAY.

1	AND FINALLY, YOUR HONOR, IN WEIGHING ALL OF THE
2	EQUITIES, I WOULD URGE THE COURT TO CONSIDER THE ISSUE OF
3	PRECEDENT HERE, BOTH IN THIS CASE AND BEYOND. THE PROTECTIVE
4	ORDER SHOULD NOT BE MADE INTO A PAPER TIGER. THAT IS TRUE IN
5	EVERY CASE, OF COURSE, BUT IT'S PARTICULARLY TRUE IN THIS CASE,
6	WHERE WE HAVE IN THE SINGLE MDL FOUR SEPARATE COMPETITOR
7	PHARMACEUTICAL COMPANIES. AND THAT'S A SENSITIVITY THAT THE
8	JPML EXPRESSLY REFERENCED WHEN IT ESTABLISHED THIS MDL.
9	THE PROTECTIVE ORDER NEEDS TO BE TAKEN SERIOUSLY.
10	THAT'S WHAT WE'RE ASKING THIS COURT TO DO WITH THIS MOTION.
11	THE COURT: OKAY. TWO QUESTIONS, IF I MAY?
12	MR. BOEHM: SURE.
12 13	MR. BOEHM: SURE.  THE COURT: THE CONFIDENTIAL INFORMATION TO WHICH
13	THE COURT: THE CONFIDENTIAL INFORMATION TO WHICH
13 14	THE COURT: THE CONFIDENTIAL INFORMATION TO WHICH YOU'RE REFERRING, IS THAT ESSENTIALLY THE INFORMATION OF
13 14 15	THE COURT: THE CONFIDENTIAL INFORMATION TO WHICH YOU'RE REFERRING, IS THAT ESSENTIALLY THE INFORMATION OF NOVO'S? IT'S THE INFORMATION THAT YOU'VE PROVIDED OTHERWISE
13 14 15 16	THE COURT: THE CONFIDENTIAL INFORMATION TO WHICH YOU'RE REFERRING, IS THAT ESSENTIALLY THE INFORMATION OF NOVO'S? IT'S THE INFORMATION THAT YOU'VE PROVIDED OTHERWISE THROUGH DISCOVERY THAT IS GOTTEN OUT OF THE LOOP, ESSENTIALLY?
13 14 15 16 17	THE COURT: THE CONFIDENTIAL INFORMATION TO WHICH YOU'RE REFERRING, IS THAT ESSENTIALLY THE INFORMATION OF NOVO'S? IT'S THE INFORMATION THAT YOU'VE PROVIDED OTHERWISE THROUGH DISCOVERY THAT IS GOTTEN OUT OF THE LOOP, ESSENTIALLY? MR. BOEHM: THAT'S CORRECT. THE ISSUE THAT IS REALLY
13 14 15 16 17 18	THE COURT: THE CONFIDENTIAL INFORMATION TO WHICH YOU'RE REFERRING, IS THAT ESSENTIALLY THE INFORMATION OF NOVO'S? IT'S THE INFORMATION THAT YOU'VE PROVIDED OTHERWISE THROUGH DISCOVERY THAT IS GOTTEN OUT OF THE LOOP, ESSENTIALLY?  MR. BOEHM: THAT'S CORRECT. THE ISSUE THAT IS REALLY AT THE CORE OF THIS IS THAT DR. FLEMING IS NOT JUST AN EXPERT
13 14 15 16 17 18	THE COURT: THE CONFIDENTIAL INFORMATION TO WHICH YOU'RE REFERRING, IS THAT ESSENTIALLY THE INFORMATION OF NOVO'S? IT'S THE INFORMATION THAT YOU'VE PROVIDED OTHERWISE THROUGH DISCOVERY THAT IS GOTTEN OUT OF THE LOOP, ESSENTIALLY?  MR. BOEHM: THAT'S CORRECT. THE ISSUE THAT IS REALLY AT THE CORE OF THIS IS THAT DR. FLEMING IS NOT JUST AN EXPERT IN THIS LITIGATION. HE IS THE FOUNDER AND THE CHIEF MEDICAL
13 14 15 16 17 18 19 20	THE COURT: THE CONFIDENTIAL INFORMATION TO WHICH YOU'RE REFERRING, IS THAT ESSENTIALLY THE INFORMATION OF NOVO'S? IT'S THE INFORMATION THAT YOU'VE PROVIDED OTHERWISE THROUGH DISCOVERY THAT IS GOTTEN OUT OF THE LOOP, ESSENTIALLY?  MR. BOEHM: THAT'S CORRECT. THE ISSUE THAT IS REALLY AT THE CORE OF THIS IS THAT DR. FLEMING IS NOT JUST AN EXPERT IN THIS LITIGATION. HE IS THE FOUNDER AND THE CHIEF MEDICAL OFFICER OF ANOTHER PHARMACEUTICAL COMPANY CALLED "EXSULIN."

THAT IS DESIGNED TO COMPETE DIRECTLY WITH INCRETIN-BASED

THERAPIES, SUCH AS THE VERY DRUGS THAT ARE AT ISSUE IN THIS

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CASE.

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NOW, PLAINTIFFS' COUNSEL, IN THEIR OPPOSITION BRIEF,
HAVE SAID WELL, DR. FLEMING AND EXSULIN, THEY ARE NOT
COMPETITORS BECAUSE THAT DRUG IS STILL BEING TESTED. IT'S NOT
YET ON THE MARKET; AND, THEREFORE, THEY ARE NOT A MANUFACTURER.

THE PROTECTIVE ORDER DEFINES COMPETITOR AS A
MANUFACTURER OR A SELLER. IF THE TERM "MANUFACTURER" IN THE
PROTECTIVE ORDER, BY DEFINITION, ONLY INCLUDED MANUFACTURERS
WHO ALSO SOLD, IT WOULD MAKE NO SENSE. IT WOULD BE COMPLETELY
REDUNDANT FOR THE PROTECTIVE ORDER TO SAY MANUFACTURER OR
SELLER.

I WOULD ALSO JUST NOTE, YOUR HONOR, WE LOOKED AGAIN
THIS MORNING AT EXSULIN'S WEBSITE THAT IS USED TO PROMOTE
ITSELF TO THE PUBLIC AND TO INVESTORS. AND I WANT TO QUOTE
DIRECTLY FROM WHAT IS STILL THERE AS OF TODAY.

QUOTE, FOR THE LAST THREE YEARS EXSULIN'S FOUNDERS

OPERATED UNDER THE RADAR TO ACHIEVE CRITICAL MILESTONES IN

MANUFACTURING, FORMULATION, ANIMAL STUDIES, AND CLINICAL TRIAL

PREPARATIONS.

HERE IS THE ISSUE: THAT PROVISION IN THE PROTECTIVE
ORDER THAT REQUIRES PLAINTIFFS' COUNSEL TO GIVE US NOTICE IF
THEY WANT TO SHARE OUR CONFIDENTIAL INFORMATION WITH A
COMPETITOR IS THERE SO THAT PLAINTIFFS' COUNSEL DON'T HAVE THE
RIGHT TO MAKE THAT DECISION ALL ON THEIR OWN. AT A MINIMUM, WE
SHOULD GET NOTICE, WE SHOULD HAVE THE OPPORTUNITY TO RESPOND;
AND, IF NECESSARY, TO BRING A MOTION BEFORE THE COURT.

WE DIDN'T HAVE THAT OPPORTUNITY. THERE WAS AN END-RUN THAT WAS MADE, AND THAT OUGHT TO BE RECTIFIED.

IN THIS CASE, THE APPROPRIATE REMEDY, BECAUSE IT
WOULD BE IMPOSSIBLE TO CROSS-EXAMINE HIM ROBUSTLY WITHOUT
DIVULGING ADDITIONAL CONFIDENTIAL INFORMATION OR FOCUSING
ADDITIONAL ATTENTION ON THE CONFIDENTIAL INFORMATION THAT
ALREADY HAS BEEN PROVIDED TO DR. FLEMING, DISQUALIFICATION IS
APPROPRIATE OR, AT A MINIMUM, HIS REPORT SHOULD BE STRICKEN AND
WE SHOULD BE DEALING WITH THE THREE-TO-FIVE PAGES OF IT THAT
ACTUALLY CONCERN THE ISSUE THAT WE WERE SUPPOSED TO BE FOCUSED
ON, WHICH IS THE NARROW ONE OF PREEMPTION.

THE COURT: GREAT. THANK YOU.

AND ANY OTHER OF THE DEFENDANTS WANT TO WEIGH IN OR JUST SUBMIT ON THE COMMENTS OF YOUR COLLEAGUES?

MR. KING: NO, YOUR HONOR.

THE COURT: AND THEN, MR. KENNERLY, YOU WANT TO TAKE

THE RESPONSE ON THAT, AS WE REALLY ARE FOCUSING MORE NOW ON THE

PROTECTIVE ORDER ASPECT OF THE MOTIONS THAT ARE HERE TODAY?

MR. KENNERLY: YES, YOUR HONOR. FIRST, THEY GOT THE LAST WORD IN BRIEFING WITH THE REPLY. SO I WANT TO ADDRESS A COUPLE ISSUES IN THERE; AND, OF COURSE, BE ABLE TO ADDRESS A NUMBER OF HIS REMARKS.

AND I NOTICED FOOTNOTE TWO OF THEIR REPLY REFERENCED

THE DICTIONARY, THE OLD STANDBY IN LEGAL ARGUMENTS. SO I

PULLED UP THE DICTIONARY AND LOOKED UP THE COMPETITOR.

COMPETITOR IS ONE WHO BUYS OR SELLS IN THE SAME MARKET.

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THAT IS NOT A MINOR ISSUE HERE. EXSULIN DOES NOT

MANUFACTURE OR SELL PRESCRIPTION MEDICATIONS. THAT'S THE

LANGUAGE OF THE PROTECTIVE ORDER: MANUFACTURER OR SELLER OF

PRESCRIPTION MEDICATIONS. THEIR EXPERIMENTAL DRUG CANNOT BE

PRESCRIBED TO ANYONE. IT CANNOT POSSIBLY COMPETE WITH ANYTHING

SOLD BY MERCK, ANYTHING SOLD BY NOVO, ANYTHING SOLD BY ELI

LILLY, ANYTHING SOLD BY AMYLIN. THEY ARE SIMPLY NOT A

COMPETITOR.

THE WAY THESE MARKETS WORK IS YOU HAVE THESE SMALLER DEVELOPMENT COMPANIES. THEY TEND TO GET GOBBLED UP OR THEY HAVE SOME SORT OF JOINT VENTURE DOWN THE LINE. THIS ISN'T A COMPETITIVE USE OF IT; IT'S A DIFFERENT FIELD OF IT ENTIRELY.

AND AGAIN, IF THEY WANTED TO HAVE MANUFACTURER OR

SELLER OR RESEARCHER OR DEVELOPER OF ANY DRUG THAT COULD

POTENTIALLY BE USED TO TREAT ANY MEDICAL CONDITION, THEY COULD

HAVE PUT THAT IN THERE.

INSTEAD, THEY CHOSE VERY SPECIFICALLY: A

MANUFACTURER OR SELLER OF A PRESCRIPTION MEDICATION. THEY

DIDN'T SAY A DEVELOPMENTAL MEDICATION. THEY DIDN'T SAY AN

EXPERIMENTAL MEDICATION. THESE ARE ALL STANDARD TERMS IN THEIR

FIELD. THEY CHOSE PRESCRIPTION MEDICATION. SOMETHING THAT

DOES NOT EXIST UNTIL YOUR NDA IS APPROVED BY THE FDA.

THERE WAS ANOTHER ARGUMENT WHICH PLAYS INTO WHAT HE WAS SAYING ABOUT HOW OUR REPORT SHOULD BE THREE PAGES. WELL,

IF YOU TAKE THEIR VIEW OF PREEMPTION IS NOT FACT-INTENSIVE,
PREEMPTION DOES NOT REQUIRE LOOKING AT MUCH, THAT PREEMPTION
CAN BE DONE ON THE BASIS OF ONE ARTICLE, THEN I SUPPOSE SO.

BUT THE TRUTH IS THAT IS NOT WHAT THE LAW ALLOWS.

THE LAW DECIDES PREEMPTION IS FACT-INTENSIVE. IT IS THEIR

BURDEN. IT IS USUALLY VERY HEAVY. IT HAS A LOT OF TESTIMONY

AND A LOT OF DOCUMENTS. AND THIS PLAYS INTO THEIR CONTENTION

THEY WERE SURPRISED THAT OUR EXPERT LOOKED AT DISCOVERY.

WELL, OF COURSE OUR EXPERT LOOKED AT DISCOVERY. THAT
WAS THE PURPOSE OF THE DISCOVERY, WAS TO FIND THE FACTUAL
INFORMATION FOR THE FACT-INTENSIVE AFFIRMATIVE DEFENSE THAT
THEY'RE BRINGING. SO THAT IS WHAT THE EXPERT HAS LOOKED AT.
THAT IS WHAT THE COURT NEEDS TO LOOK AT.

IF WE HAD HAD OUR EXPERT SAY I LOOKED AT ONE

DOCUMENT -- OR, LIKE THEIR EXPERT. THEIR EXPERT LOOKED AT, I

THINK, THREE DOCUMENTS. I DON'T SEE HOW THAT COULD POSSIBLY

SURVIVE DAUBERT. I DON'T SEE HOW YOU COULD POSSIBLY HAVE AN

EXPERT MAKE A PREDICTION ABOUT ANYTHING ABOUT THE FDA ON THE

BASIS OF THREE DOCUMENTS.

THAT IS NOT HOW ANY OF THEIR CONSULTANTS WOULD WORK.

IT IS NOT WHAT ANYONE ATTEMPTING TO ADDRESS THE FDA WOULD

ACTUALLY DO.

SO FOR OUR CASE, HE LOOKED THROUGH THE MATERIALS

AVAILABLE FOR THEM. AND AGAIN, THE IDEA THAT WELL, INSTEAD, WE

ARE SUPPOSED TO HAVE AN IPSE DIXIT ASSERTION ABOUT WHAT THEY

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READ THE EGAN ARTICLE TO MEAN. THAT IS NOT PREEMPTION. THAT HAS NEVER BEEN OUR PREEMPTION WORK.

IN FACT, YOUR HONOR DENIED THE SAME ARGUMENT TO THE ONGLYZA DEFENDANTS. THEY SAID IT'S A MOTION TO DISMISS. YOU DON'T NEED TO GET INTO THE FACTS. IT WAS DENIED. WE WENT INTO DISCOVERY. WE WENT INTO DISCOVERY HERE. WE ARE IN THE FACTS.

SO I DON'T THINK THAT IS AN APPROPRIATE STANDARD. I
DON'T THINK IT'S AN APPROPRIATE REMEDY. THE REMEDY WOULD BE
CROSSING OUT ALL THE FACTS OF PREEMPTION. THEN HOW DO THEY
EVEN GET THE PREEMPTION THEMSELVES?

WHICH MOVES TO WHAT IT IS THAT HE HAS. AND I NOTICED THAT MR. BOEHM'S ARGUMENT FOCUSED ON WE LOST THE OPPORTUNITY TO OBJECT. WE SHOULD HAVE HAD THE OPPORTUNITY TO OBJECT. NOW, OUR VIEW IS HE DOESN'T FALL WITHIN THE DEFINITION.

BUT LET'S ASSUME THEY HAD THE OPPORTUNITY TO OBJECT.
THEN WHAT? WHAT WOULD THEY SAY WAS INAPPROPRIATE OR COULD NOT
BE GIVEN TO THE EXPERT? BECAUSE BEAR IN MIND THIS IS A
MULTIPLE-DEFENDANT LITIGATION. THEY HAVE GIVEN US THOUSANDS OF
REDACTIONS. THEY HAVE REFUSED TO PROVIDE US MILLIONS OF
DOCUMENTS. EVERYTHING WE EVER LOOK AT HAS SOMEWHERE ON IT A
REDACTION. AND WHY? BECAUSE AT LEAST THEY CONTEND WHY: THOSE
REDACTIONS RELATE TO THE ACTUAL TRADE SECRETS. THE FACT THAT
YOU HAD A CERTAIN NUMBER OF PANCREATIC CANCER INCIDENTS IN YOUR
TRIAL IS NOT A TRADE SECRET. IT DOES NOT HELP A COMPETITOR DO
ANYTHING. IT DOES NOT AID THEIR MANUFACTURING. IT DOES NOT

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HELP THEM WITH PRICING. IT'S SIMPLE SAFETY DATA ABOUT HOW THE DRUG HAS WORKED IN THE ENVIRONMENT.

SO AGAIN, THEY CAN'T SHOW ANY OF THIS WAS IMPROPER TO GIVE TO THE EXPERTS BECAUSE THE TRUE CONFIDENTIALITY HERE, THE TRADE SECRETS, HAVE ALREADY BEEN PRESERVED BEFORE ANYTHING EVER MADE IT TO US. WE DON'T KNOW PRICING DATA ON JANUVIA. WE DON'T KNOW HOW YOU MAKE BYETTA. WE HAVEN'T SOUGHT IT. WE HAVEN'T SOUGHT TO REMOVE THE REDACTIONS THEY CLAIM ARE RELATED TO IT. WE HAVE STUCK WITH THE PARTS THAT ARE NOT TRULY CONFIDENTIAL. THE PARTS THAT DO NOT AID ANY COMPETITOR WOULD NOT AID US. AND WE HAVE ABIDED BY THAT.

SO I THINK IF YOUR HONOR IS GETTING TO THE ISSUE OF WHAT ARE ALTERNATIVE SANCTIONS, WHAT IS THE PREJUDICE HERE, THE DEFENDANTS HAVEN'T EVEN ARGUED ONE. THE PREJUDICE THEY ARGUE IS WE LOST THE OPPORTUNITY TO OBJECT. WELL, THAT IS NOT WHAT YOU BASE A SANCTION ON. THAT IS NOT WHAT YOU BASE ANYTHING ON. YOU BASE IT ON HARM. SO WHAT WOULD THE HARM HAVE BEEN?

IF WE HAD GIVEN THEM NOTICE IN ADVANCE, WHAT WOULD THEY HAVE DONE? THEY WOULD HAVE SAID, "WELL, YOU CAN'T PROVIDE TO HIM THE UNDERLYING DATA OF THE ANGLE META-ANALYSIS." I DON'T THINK YOUR HONOR WOULD HAVE SAID THAT WAS APPROPRIATE.

"YOU CAN'T PROVIDE TO THEM THE DEPOSITION OF OUR EPIDEMIOLOGIST." I DON'T THINK YOUR HONOR WOULD HAVE SAID THAT THAT WAS AN APPROPRIATE OBJECTION.

WHAT HE REVIEWED AND WHAT HE CITES IN HIS REPORT, ALL

OF IT, IS RELATING TO A CBE. IT'S RELATING TO PREEMPTION. IT
HAS NOTHING TO DO THAT WOULD AID EXSULIN. IT HAS NOTHING TO DO
TO AID ANY OF THE DEFENDANTS HERE WITH ONE ANOTHER.

AND I SAID THIS PREVIOUSLY, BUT I DO THINK IT NEEDS
TO BE REITERATED. HIS REPORT IS NOT A GENERAL CAUSATION
REPORT. HE IS NOT AN EXPERT IN EVERY ONE OF THOSE FIELDS. HE
IS AN EXPERT ON THE FDA. EVERY WORD IN THAT, EVERY SENTENCE IN
THAT IS THERE TO SHOW WHAT THE FDA WOULD DO IN RESPONSE TO A
CBE. DOES IT GET HEAVILY INTO THE SCIENCE? IT DOES. IT HAS
TO.

THE DEFENDANT CANNOT SAY THE FDA WOULD HAVE REJECTED

A BAD CBE I SENT IT. IF I SENT A ONE-LINE "I WANT TO CHANGE

THIS," AND THE FDA REJECTED IT, THEY HAVE PROVEN NOTHING. WHAT

THEY HAVE TO PROVE IS WHAT THEY WOULD HAVE ACTUALLY SHOWN THE

FDA IN A GENUINE CBE.

WELL, THEY WOULD NEED TO SHOW THE EVIDENCE THEY HAVE WITH IT. THEY WOULD NEED TO SHOW HEALTH CANADA. THEY WOULD NEED TO SHOW THE IMBALANCE OF PANCREATIC CANCER UNDER TRIALS.

THIS IS THE SAME EVIDENCE THAT DR. FLEMING HAD IN HIS OWN POSSESSION.

SO GETTING TO THE PREJUDICE THAT I HEARD SPECIFIED.

ONE WAS LOST OPPORTUNITY. ANOTHER ONE WAS, I THINK, THE

DIFFICULTY OF CROSS-EXAMINING HIM.

AND TO BE CANDID, I DON'T QUITE UNDERSTAND THAT.

BECAUSE HE REFERENCES MATERIALS THAT WERE AVAILABLE TO HIM, BUT

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HIS REPORT, IN IT, SAYS WHAT SPECIFIC DOCUMENT HE IS LOOKING AT AND WHERE HE IS RELYING ON IT. SO THERE IS NO PREJUDICE OFF OF THAT. THAT SUM TOTAL, I THINK, IS PROBABLY SOME 40 OR 50 DOCUMENTS THAT HE HAS CITED IN THE CONTEXT OF HIS REPORT. THEY CAN USE THOSE DOCUMENTS IN CROSS-EXAMINING HIM. I DON'T KNOW WHY THEY FEEL THAT'S IMPOSSIBLE, THAT'S DIFFICULT. THAT'S STANDARD CROSS-EXAMINATION.

AND I THINK THERE WAS A REFERENCE TO THEY MIGHT HAVE
TO DISCLOSE OTHER INFORMATION TO HIM IN ORDER TO CROSS-EXAMINE
HIM. I CAN'T ENVISION HOW THAT WOULD HAPPEN. EVERYTHING HE
REFERENCES IN THERE IS PART OF THE OVERALL DISCOVERY. IF THEY
HAVE A DOCUMENT THAT WAS NOT PRODUCED IN DISCOVERY TO US, WELL,
YEAH, I THINK THEY WOULD HAVE DIFFICULTY CROSS-EXAMINING HIM ON
THAT BECAUSE IT WOULD BE, IN ESSENCE, ADMITTING A DISCOVERY
VIOLATION.

SO, AGAIN, THIS COMES BACK TO IF YOUR HONOR DOES FIND A VIOLATION AND IS LOOKING FOR WHAT IS THE SANCTION OFF OF THIS, WELL, WHAT'S THE HARM TO THEM OFF OF THIS? A LOST OPPORTUNITY IS NOT A HARM. AN IDEA THAT I CAN'T CROSS-EXAMINE HIM ON MY OWN DOCUMENTS THAT HE DIDN'T REFERENCE IN HIS REPORT, THAT'S NOT A HARM, EITHER.

AND THIS IDEA ABOUT THE PROTECTIVE ORDER BEING A

PAPER TIGER. IT IS NOT A PAPER TIGER. THEY THEMSELVES PUT IN

A LOT OF EFFORT TO IT TO KEEP OUT TRADE SECRETS, TO KEEP OUT

INFORMATION THEY DIDN'T WANT EACH OTHER TO HAVE. WE DIDN'T

FIGHT THEM ON THAT. WE LET THEM HAVE NUMEROUS REDACTIONS.

MIGHT THERE BE RELEVANT INFORMATION UNDERLYING THEM?

PERHAPS SO. WE WEREN'T GOING TO BRING THE COURT IN ON THAT.

WE WEREN'T GOING TO HAVE A FIGHT OVER IT. WE DON'T WANT TRADE

SECRET INFORMATION. WE DON'T WANT PRICING DATA. WE DON'T WANT

MANUFACTURING DATA. WE HONORED IT.

AND, YOUR HONOR, I DO THINK THERE IS AN IMPORTANT

CODA ON THIS. WE FILED HIS REPORT ENTIRELY UNDER SEAL. THE

DEFENDANTS THEMSELVES PUT A COPY OF HIS REPORT ON THE DOCKET.

I'M NOT SURE WHY. PARTIALLY REDACTED, BUT STILL HAD THE

ESSENCE OF HIS CONCLUSIONS THERE, AVAILABLE FOR THE WHOLE WORLD

TO SEE. NOT ONE ARTICLE IN IT. NOT ONE PRESS REPORT.

NOTHING. YOUR HONOR STRIKES IT FROM THE DOCKET.

THEN WE COME TO THIS MOTION. THEY ACCUSE DR. FLEMING PUBLICALLY, ON THE DOCKET, OF BREACHING HIS CONFIDENTIALITY AGREEMENT. AND YOU CAN SEE HERE THEY STILL CAN'T POINT TO ANYTHING SPECIFICALLY DOING IT. WE JUST HAD AN ARGUMENT OVER THE SUNSET PROVISIONS. THEY STILL CAN'T POINT TO ANYTHING SHOWING IT, BUT THEY PUT THAT ON THE PUBLIC DOCKET. THE PART WE'RE TALKING ABOUT HERE, THE SEPARATE MOTION, THE WHOLE THING WAS ON THE PUBLIC DOCKET. WITHIN THREE DAYS OF THAT GOING ON THERE, THERE IS A LAW360 STORY, BLASTING DR. FLEMING, QUOTING FROM THEIR BRIEFS.

SO IF WE ARE TALKING HERE OF WHO HAS A GENUINE CONCERN FOR CONFIDENTIALITY, WHO IS GENERALLY FOLLOWING THESE

PROTECTIVE ORDERS, I WOULD SUBMIT TO YOU THE PLAINTIFFS ARE,
THE DEFENDANTS ARE NOT.

THE COURT: OKAY. WELL, THANK YOU.

DID YOU WANT TO SAY ANYTHING, MR. BOEHM, IN RESPONSE?

MR. BOEHM: IF I MAY.

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THE COURT: YOU MAY.

MR. BOEHM: YOUR HONOR, SOME OF THE ARGUMENTS THAT WE'VE JUST HEARD FROM MR. KENNERLY WOULD HAVE BEEN INTERESTING TO HAVE HEARD DURING THE 14-DAY PERIOD DURING WHICH WE SHOULD HAVE BEEN ABLE TO ADDRESS ARGUMENTS PURSUANT TO THE TERMS OF THE PROTECTIVE ORDER. UNFORTUNATELY, WE DID NOT HAVE THAT OPPORTUNITY.

THE PROTECTIVE ORDER OUGHT TO BE HONORED. WE DIDN'T HAVE A CHANCE TO DEFEND OUR RIGHTS UNDER THE PROTECTIVE ORDER.

AND WITH RESPECT TO WHETHER OR NOT THIS COURT WOULD HAVE MAINTAINED OUR CONFIDENTIALITY DESIGNATIONS, LET ME JUST POINT OUT ONE VERY IMPORTANT FACT.

MANY OF THE DOCUMENTS THAT ARE CITED IN DR. FLEMING'S REPORT OR ARE INCLUDED IN HIS LIST OF RELIANT MATERIALS HAVE ALREADY BEEN THE SUBJECT OF MOTIONS TO SEAL, MOTIONS THAT HAVE BEEN GRANTED. THESE DOCUMENTS HAVE ALREADY BEEN UPHELD AS CONFIDENTIAL BY COURT ORDER.

I'M GLAD WE HAD THE OPPORTUNITY TO CLARIFY THAT WE

ARE REALLY TALKING ABOUT TWO DIFFERENT MOTIONS. I BELIEVE THAT

MR. KENNERLY TALKED AS IF THE CONCERN, THE PREJUDICE FOR US IS

THAT SOMEHOW DR. FLEMING HAD DOCUMENTS ALREADY THAT WE THEN
WERE GOING TO BE FORCED TO CROSS-EXAMINE HIM ABOUT. THAT'S NOT
THE PREJUDICE.

THE PREJUDICE IS THAT HE IS A COMPETITOR. AND WITH RESPECT TO THIS MOTION WAS GIVEN DOCUMENTS THAT HE OTHERWISE NEVER WOULD HAVE HAD. IN SOME CASES THESE DOCUMENTS INCLUDE SENSITIVE CLINICAL AND PRECLINICAL STUDY DESIGNS AND PROTOCOLS, REGULATORY CORRESPONDENCE THAT HAS BEEN MARKED "ATTORNEYS' EYES ONLY," WHICH MEANS THAT I CAN'T EVEN SHOW IT TO MY OWN CLIENT IF IT COMES FROM ANOTHER COMPANY.

HE IS A COMPETITOR; THAT'S THE POINT. THAT IS WHAT MAKES IT DIFFICULT TO CROSS-EXAMINE HIM IN A DEPOSITION. WE HAVE TO USE OUR CONFIDENTIAL DOCUMENTS TO BE ABLE TO DO THAT ROBUSTLY AND EFFECTIVELY. AND THAT IS NOT SOMETHING WE WANT TO DO OR SHOULD BE FORCED TO HAVE TO DO. AND WE WOULDN'T HAVE BEEN IF WE HAD AN OPPORTUNITY TO OBJECT, AS WE SHOULD HAVE BEEN.

THE COURT: OKAY. WELL, THANK YOU. I WILL TAKE THE
TWO MOTIONS UNDER SUBMISSION. I WANT TO GO BACK AND RECONSIDER
OR CONSIDER, AGAIN, ALL THE PRECISE POINTS THAT HAVE BEEN MADE
AND PUT INTO CONTEXT THE ANSWERS TO THE QUESTIONS YOU FOLKS
WERE KIND ENOUGH TO GIVE.

I WISH I COULD DISTILL IT DOWN AND RESOLVE IT THIS AFTERNOON, BUT THAT IS JUST NOT GOING TO BE FAIR OR BEST PRACTICE FOR ANYBODY. SO THOSE MATTERS ARE SUBMITTED.

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AND I KNOW WE ALSO HAVE STATUS ASSOCIATED WITH A CASE
ON THE BURNER TODAY. AND LOOKING AT THE JOINT REPORT THAT WAS
SUBMITTED, THE FIRST OF WHICH WOULD BE THE STATUS OF
PREEMPTION, GENERAL CAUSATION EXPERTS' SCHEDULE, WHO WANTS TO
TELL ME ABOUT WHERE WE ARE, WHAT THAT MEANS, AND WHERE WE NEED
TO GO?

IT SOUNDS LIKE A LOT OF WHAT HAPPENS NEXT WILL DEPEND ON WHETHER OR NOT FLEMING IS DISQUALIFIED IN WHOLE OR IN PART OR IN SOME OTHER WAY.

AND SO FROM THE PLAINTIFFS' STANDPOINT,

MR. SHKOLNIK -- YOU'RE ABOUT TO STAND -- GO AHEAD AND TELL ME
WHAT YOU THINK WE SHOULD ADDRESS NEXT.

MR. SHKOLNIK: WELL, YOUR HONOR, MAYBE I'M NOT CLEAR ON WHAT THE NEXT STEP WOULD BE. BUT CERTAINLY THE COURT'S DECISION ON THE DISQUALIFICATION IS GOING TO AFFECT US AS IT RELATES TO A REGULATORY EXPERT AND AN ENDOCRINOLOGY EXPERT. I THINK IT'S FAIR TO SAY THAT WE ARE ON TRACK FOR EXCHANGE OF GENERAL CAUSATION EXPERTS, AS HAS BEEN ORDERED BY THE COURT.

THERE ARE A COUPLE OF ITEMS THAT WE'RE STILL WORKING WITH THE DEFENDANTS ON IN TERMS OF SOME DATA, BUT THAT IS NOT AFFECTING THE EXPERT REPORTS AND THE SCHEDULE DATE.

SOME OF THESE MATTERS MAY BE NECESSARY FOR EITHER REBUTTALS, REPLY EXPERT REPORTS, OR POSSIBLY SUPPLEMENTS LATER ON DOWN THE ROAD, BUT NOTHING, AS WE SEE IT NOW, IS GOING TO AFFECT EXPERT REPORTS THAT ARE PLANNED FOR THE 17TH, I THINK IT

IS. IS MY DATE RIGHT? 19TH. I DIDN'T HAVE MY NOTES IN FRONT OF ME. SO AS TO THE EXPERT REPORTS, WE ARE FINE.

AS TO DR. FLEMING, THAT IS A BIG ISSUE THAT IS HANGING OVER US.

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THE COURT: AND I APPRECIATE THAT.

MR. SHKOLNIK: AS REQUESTED BY THE DEFENDANT, ALL DEFENDANTS, IN DECEMBER -- AND I DON'T KNOW WHICH DATE -- WE IMMEDIATELY STOPPED INTERACTING WITH DR. FLEMING IN THE AREA OF THE GENERAL CAUSATION. WE STOPPED PROVIDING ANY ADDITIONAL INFORMATION OR GOING OVER ANY INFORMATION, AND SECURED THE INFORMATION THAT HAD PREVIOUSLY BEEN PROVIDED TO HIM.

SO WE ARE CERTAINLY BEHIND THE EIGHT BALL BY AT LEAST 60 TO 75 DAYS WITH HIS OPINIONS IN THAT AREA, IN THE AREAS OF ENDOCRINOLOGY AND GENERAL CAUSATION. SO ONCE WE SEE WHAT THE COURT IS GOING TO DO, WE ARE DEFINITELY GOING TO NEED ADDITIONAL TIME AS TO THAT EXPERT. AND I THINK I MAKE THAT REPRESENTATION AT THIS TIME.

THE COURT: I APPRECIATE THAT. I HAVEN'T HEARD FROM
THE DEFENSE, OF COURSE, BUT I WONDER IF IT WOULDN'T BE BETTER
TO SET THIS ISSUE OF STATUS OFF SEVERAL WEEKS, AND IN THE
INTERIM MY DECISION WOULD ISSUE. IT WOULD GIVE YOU A CHANCE TO
PUT THAT INTO THE CALCULUS OF THE ISSUE OF WHERE WE GO NEXT,
AND THEN WE COULD HAVE MAYBE A MORE MEANINGFUL DISCUSSION, AS A
THOUGHT.

MR. SHKOLNIK: I THINK THAT IS A VERY GOOD IDEA, YOUR

HONOR. I THINK WE ALL WOULD BENEFIT BY THE GUIDANCE OF YOUR OPINION AND THEN A STATUS.

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THE COURT: BECAUSE THEN YOU WOULD KNOW WHICH WAY YOU'RE GOING.

MR. MARVIN, DID YOU HAVE A COMMENT IN THAT REGARD, OR THOUGHTS, SIR?

MR. MARVIN: YOUR HONOR, DOUGLAS MARVIN REPRESENTING

MERCK. I THINK I CAN SPEAK ON BEHALF OF THE OTHER DEFENDANTS,

ALTHOUGH THEY CAN GET UP AND LET ME KNOW IF I'M NOT.

DIRECTION. WE ALL RECOGNIZE THAT A RULING ON THE FLEMING MOTIONS CAN HAVE SOME BEARING ON THE SCHEDULE. SO IN LIGHT OF WHAT YOUR HONOR JUST MENTIONED ABOUT RECONVENING, ONCE WE HAVE THOSE RULINGS PERHAPS WE CAN -- ONCE WE GET THE RULINGS, DISCUSS IT WITH THE PLAINTIFFS AND COME UP WITH AN AGREED SCHEDULE THAT WE WOULD PROPOSE TO YOUR HONOR. BUT IF NOT, WE WOULD COME BACK TO YOUR HONOR WITH BOTH PARTIES' THOUGHTS ON THAT SCHEDULE.

THE COURT: OKAY. WOULD IT BEHOOVE US, DO YOU THINK,

SIR -- AND IF ANYBODY ELSE DIFFERS FROM MR. MARVIN'S COMMENTS,

CERTAINLY SAY SO -- TO SET THINGS OUT MAYBE THREE WEEKS FOR A

SCHEDULING CONFERENCE? DOES THAT SEEM TOO SHORT, TOO LONG? I

DON'T KNOW HOW LONG, FRANKLY, IT WILL TAKE ME TO DECIDE AND

AUTHOR THE DECISION THAT WILL GIVE YOU THE GUIDANCE THAT YOU

NEED. BUT I'M THINKING THREE, FOUR WEEKS -- THAT MAY BE THE

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MAXIMUM	FOR A S	TATUS -	WOUI	D BE	PRUDE	int. 1	T PUTS	SOME	
PRESSURE	ON ME,	BUT I	DON'T	WANT	TO PU	JT UNDU	JE PRESS	SURE ON	JOY
FOLKS IN	THE WA	KE OF V	JHAT T	MTGHT	DO T	TO YOU	OR FOR	YOU.	

MR. SHKOLNIK: YOUR HONOR, FROM THE PLAINTIFFS'

STANDPOINT, THREE, FOUR WEEKS WOULD BE FINE. IT GIVES YOU

ENOUGH TIME TO WRITE WHATEVER OPINION YOU HAVE TO, AND IT GIVES

US TIME TO WORK TOGETHER TO COME UP WITH A PROPOSAL. AND IF WE

CAN'T, THEN TO COME TO THE COURT AND ASK THE COURT TO SET IT.

THE COURT: OKAY. MR. MARVIN AND FELLOW DEFENDANTS?

MR. MARVIN: I THINK THAT IS FINE, YOUR HONOR, IF WE JUST MOVE THINGS BACK THREE WEEKS OR SO.

AND AS I SAY, ONCE WE GET THE RULING, HOPEFULLY WE CAN ALL COME TO AN AGREEMENT WITHIN A WEEK OR SO. BUT CERTAINLY WITHIN TWO WEEKS AFTER THAT I WOULD HOPE THAT WE COULD HAVE IT RESOLVED.

THE COURT: OKAY. EVERYONE ELSE CONCUR ON THE DEFENSE SIDE, THE LADIES AND GENTLEMEN?

WHY DON'T WE, OUT OF AN ABUNDANCE OF CAUTION, SAY

APRIL 2ND. IT WILL GIVE ME FOUR WEEKS. AND IF IT TAKES A

COUPLE WEEKS TO ADJUST US TO THE WRITTEN WORK PRODUCT THAT I

ISSUE, THAT GIVES YOU A COUPLE WEEKS TO RALLY THE TROOPS AND

DECIDE.

I WOULDN'T WORRY SO MUCH ABOUT HAVING AN ADVANCE
SUBMISSION TO ME. WE CAN JUST TALK ABOUT IT WHEN WE GET HERE.

AND IT CAN BE TELEPHONIC FOR ALL CONCERNED OR FOR THOSE THAT

	5 /
1	PREFER TO SAVE WEAR AND TEAR. BUT WOULD SOMETHING LIKE
2	APRIL 2ND AT 2:00 WORK? THAT IS ANOTHER THURSDAY.
3	MR. SHKOLNIK: THAT WOULD BE FINE, YOUR HONOR.
4	THE COURT: JUDGE HIGHBERGER, ARE YOU STILL WITH US,
5	SIR?
6	JUDGE HIGHBERGER: YES. APRIL 2ND WOULD WORK IN THE
7	AFTERNOON. YOU ARE GOING TO LOSE ME NOW, BUT I TRUST MY LAW
8	CLERK MATTHEW LAHANA IS ON THE LINE. HE SHOULD HAVE ACCESS TO
9	MY CALENDAR, EVEN AS I DEPART. BUT APRIL 2ND IN THE AFTERNOON
10	WOULD BE FINE.
11	THE COURT: GIVEN YOUR TIME IS SHORT, SIR, IS THERE
12	ANYTHING ELSE YOU WOULD LIKE TO REPORT BY WAY OF STATUS OR
13	COMMENT WITH REGARD TO THE JCCP AS IT RELATES TO OUR CASE IN
14	THE FEDERAL COURT?
15	JUDGE HIGHBERGER: NO. NO, I DON'T THINK SO. I'M
16	GLAD YOU HAVE TO DECIDE THE TWO MOTIONS IN FRONT OF YOU AND NOT
17	ME.
18	THE COURT: I'M GLAD FOR YOU, TOO. WELL, THANK YOU.
19	FEEL FREE TO DROP OFF WHEN YOU NEED TO.
20	WE'LL TALK NOW ABOUT THE THYROID CASES THAT ARE
21	CONSOLIDATED HERE, UNLESS THERE IS SOMETHING ELSE ANYONE WANTS
22	TO RAISE ON THE MDL, THE PANCREATIC CANCER SIDE? SEEING NOBODY
23	MAKE A MOVE.
24	WHAT ABOUT THE THYROID CASES? HOW ARE WE DOING

THERE? WHO WOULD LIKE TO TAKE THAT UP?

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THOMPSON: YOUR HONOR, THIS IS RYAN THOMPSON. 1 MR. 2 CAN YOU HEAR ME IN THE COURT? 3 THE COURT: I CAN. THOMPSON: OKAY. I HAD ONE ISSUE THAT I WANTED 4 TO PREVIEW FOR THE COURT AS IT RELATES TO THE MDL PANCREATIC 5 CANCER CASES. 6 7 THE COURT: OKAY. 8 THOMPSON: AND AT THIS TIME IT'S MORE OF A 9 PREVIEW OF AN UPCOMING POTENTIAL ISSUE THAT I WANTED TO APPRIZE 10 YOUR HONOR ON AND GIVE YOU A LITTLE BIT OF BACKGROUND AS TO WHERE WE ARE, IN THE EVENT THAT THIS COMES TO THE COURT IN THE 11 12 FUTURE. THERE WAS RECENTLY A PUBLICATION DONE THAT WAS OUT OF 13 THE UNIVERSITY OF TEXAS. SOME OF THE AUTHORS OF THAT WERE 14 15 DR. FOLLI, DR. DEFRONZO AND OTHERS. THE TITLE OF THAT 16 PUBLICATION WAS CHRONIC CONTINUOUS EXENATIDE INFUSION DOES NOT 17 CAUSE PANCREATIC INFLAMMATION AND DUCTAL HYPERPLASIA IN 18 NON-HUMAN PRIMATES. 19 AND WHAT THAT STUDY WAS IS IT LOOKED AT 52 BABOONS 2.0 THAT HAD BEEN INFUSED WITH EXENATIDE AND LOOKED AT THEIR PANCREATA AFTER INFUSION OF EXENATIDE. AND ONE OF THE THINGS 21 22

PANCREATA AFTER INFUSION OF EXENATIDE. AND ONE OF THE THINGSTHAT WE THINK WOULD BE USEFUL TO THE COURT, AND THAT WE HAVE BEEN TRYING TO OBTAIN, IS WHETHER OR NOT THE PANCREATA FROM THOSE BABOONS SHOWED SIGNS OF PROLIFERATION.

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THERE WERE A NUMBER OF SLIDES TAKEN FROM THOSE

2.0

ANIMALS DURING THE STUDY, BOTH BEFORE AND AFTER THE INFUSION.
ONE OF THOSE SETS OF SLIDES WAS MARKED WITH A STAIN THAT IS
KNOWN AS KI-67 OR MIB-1. AND WHAT THAT IS DESIGNED TO SHOW IN
THE PANCREAS IS WHETHER THERE ARE PROLIFERATION MARKERS OR
PROLIFERATION IS ACTUALLY OCCURRING THEN. AND SO WHAT THAT
WOULD ALLOW US TO DO IS SEE WHETHER OR NOT INFUSION WITH
EXENATIDE DOES ACTUALLY SHOW SIGNS OF PROLIFERATION THERE.

WHEN WE FOUND OUT ABOUT THIS PUBLICATION AND THE STUDY THAT WAS GOING ON -- IT'S ONE THAT WAS FUNDED BY THE NIH AND ALSO BY ELI LILLY AND AMYLIN -- WE SUBPOENAED THE UNIVERSITY OF TEXAS AND DR. FOLLI IN AUGUST OF 2014.

WE SUBSEQUENTLY, AFTER THAT, ALSO SERVED A SUBPOENA
ON DR. DEFRONZO. DR. FOLLI AND DR. DEFRONZO WERE TWO OF THE
LEAD AUTHORS ON THAT STUDY. WE SUBSEQUENTLY LEARNED, AFTER
THAT, THAT DR. FOLLI WAS IN BRAZIL, ON SABBATICAL OUT OF THE
COUNTRY, FOR A YEAR. SO WE COULD NOT GET HIM FOR A DEPOSITION,
BUT WHAT HE DID DO IS PROVIDE US WITH A SMALL DOCUMENT
PRODUCTION RELATED TO THAT STUDY.

WHEN WE GOT THAT, WE DISCOVERED THAT ANOTHER COMPANY
IN TEXAS HAD SLIDES FROM THAT STUDY. AND WE WANTED TO HAVE THE
OPPORTUNITY TO OBTAIN, REVIEW AND SCAN THOSE SLIDES.

IN OCTOBER OF 2014, WE SERVED A SUBPOENA ON A COMPANY
IN SAN ANTONIO CALLED "SOUTHWEST RESEARCH INSTITUTE." WE LATER
FOUND OUT, AFTER GETTING ADDITIONAL DOCUMENT PRODUCTION AND
TALKING WITH SOUTHWEST RESEARCH INSTITUTE, THAT THE COMPANY

THAT ACTUALLY HAD THEM WAS A COMPANY CALLED "TEXAS BIOMEDICAL RESEARCH INSTITUTE."

WE SERVED A SUBPOENA ON THEM IN NOVEMBER OF 2015

(SIC) AND WERE ABLE TO GET A FAIRLY ROBUST DOCUMENT PRODUCTION

FROM TEXAS BIOMED. AND THEN IN DECEMBER BEGAN MAKING

ARRANGEMENTS FOR US TO BRING IN STAINING EQUIPMENT FROM

CALIFORNIA AND CONSULTANTS FROM AROUND THE WORLD TO COME IN AND

SCAN THOSE SLIDES.

IN JANUARY OF 2015, WE BEGAN THE PROCESS AT TEXAS BIOMED OF SCANNING THOSE SLIDES. WE QUICKLY DISCOVERED DURING THAT PROCESS -- WE HAD APPROXIMATELY 200 SLIDES THAT WE WERE ABLE TO SCAN, BUT THE SLIDES THAT WE WERE MOST INTERESTED IN, THE ONES THAT WOULD SHOW PROLIFERATION IN THE PANCREAS, THE KI-67 OR THE MIB-1 SLIDES, WERE NOT THERE.

WE WENT TO U.T., WHO IS REPRESENTED BY THE TEXAS
ATTORNEY GENERAL. WE WENT TO TEXAS BIOMED, TRYING TO FIGURE
OUT WHERE THESE SLIDES WERE. SINCE WE HAD THE EQUIPMENT THERE,
WE OBVIOUSLY WANTED TO BE ABLE TO SEE THOSE SLIDES BECAUSE THEY
WOULD BE THE ONES THAT WOULD BE THE MOST INFORMATIVE TO US, AND
WE BELIEVE TO THE COURT, IN LOOKING AT WHAT EXENATIDE DOES IN
THE PANCREAS, ESPECIALLY WHEN WE CAN SEE WHETHER OR NOT
PROLIFERATION IS OCCURRING.

WHAT WE DISCOVERED ON FEBRUARY 5TH IS THAT THOSE
SLIDES, OUT OF ALL THE SLIDES, HAD LEFT THE COUNTRY. NOW,
THERE IS SOME CONFUSION AS TO WHETHER OR NOT THEY WERE ACTUALLY

EVER IN THE COUNTRY. TEXAS BIOMED HAS SAID THAT THEY WERE;
OTHERS HAVE SAID THAT THEY WERE NOT.

BUT AT THE END OF THE STORY, IRRESPECTIVE OF WHO IS RIGHT, WHAT WE UNDERSTAND NOW IS THAT THOSE SLIDES ARE IN ITALY WITH ONE OF THE OTHER STUDY AUTHORS, A DOCTOR BY THE NAME OF DR. LA ROSA.

I HAVE TRIED E-MAIL CORRESPONDENCE WITH DR. LA ROSA
AND OTHERS. WE HAVE SENT ADDITIONAL SUBPOENAS TO U.T. TO TRY
AND FIGURE OUT WHERE THESE SLIDES ARE, IF THEY ARE ALL ACTUALLY
IN ITALY AND WHEN THEY LEFT THE UNITED STATES, SO THAT WE CAN
FINISH THIS PROJECT AND OBTAIN THAT INFORMATION.

I HAVE ALSO RECENTLY REACHED OUT TO THE DEFENDANTS IN THIS CASE, COUNSEL FOR AMYLIN AND ELI LILY, TO SEE WHETHER OR NOT THEY HAD CONTROL OVER THOSE SLIDES, AS WELL. AND I WILL MAKE AND TAKE NO POSITION ON WHETHER OR NOT THEY DO AT THIS TIME, BUT I DID WANT TO UPDATE THE COURT THAT COUNSEL FOR AMYLIN HAS RECENTLY OFFERED TO CONFER WITH US ON WHETHER OR NOT THEY WOULD BE ABLE TO ASSIST IN FACILITATING THE REVIEW OF THOSE SLIDES IN ITALY.

THAT IS AN OFFER. I SENT THEM AN E-MAIL TODAY,
THANKING THEM FOR THAT. WE BELIEVE AS ONE OF THE COMPANIES
THAT FUNDED THAT STUDY, THAT A REQUEST FROM THEM TO ALLOW US TO
SCAN AND REVIEW THOSE SLIDES IN ITALY WOULD GO A LONG WAY. AND
WE INTEND TO HAVE CONVERSATIONS WITH THEM IN THAT REGARD IN THE
NEAR FUTURE.

	BUT	ΓI W.	ANTED	TO A	APPR:	IZE T	HE C	OURT	OF	THE	FACT	TH	AT	WE
DO HAV	JE MULTI	IPLE	SUBPO	ENAS	OUT	. AN	D WE	ARE	TRY	YING	TO F	IND	)	
THESE	SLIDES	THAT	WE T	HINK	ARE	VERY	IMP	ORTAI	I TI	O US	S TO	BE	ABL	Ε
TO REV	JIEW.													

AND THERE IS NOT AN ISSUE THAT IS RIPE FOR THE COURT TODAY, BUT I WANTED TO GIVE YOU SOME BACKGROUND ON WHAT HAS GONE ON OVER THE LAST HALF-YEAR-PLUS, AND HOW CLOSE WE ARE TO BEING ABLE TO GET THOSE.

I DO NOT AND AM NOT REQUESTING THAT WE HAVE ANY KIND OF AN EXTENSION ON OUR EXPERT REPORTS, BUT IT COULD BE THAT AFTER OUR REPORTS ARE IN, THAT INFORMATION COMES. AND IF IT DOES, I DO BELIEVE THAT WE WOULD HAVE AN OBLIGATION TO SUPPLEMENT.

BUT MORE THAN ANYTHING, THERE COULD BE SUBPOENAS THAT WE HAVE OUTSTANDING THAT COULD REQUIRE THE COURT'S INTERVENTION IN THE NEAR FUTURE. AND AS A RESULT, I WANTED TO GIVE YOU A LITTLE BIT OF A BACKGROUND AND PREVIEW ON THAT, IN THE EVENT IT COMES UP.

THE COURT: OKAY. WELL, THANK YOU. AND I APPRECIATE
THE HEADS-UP ON WHAT'S OUT THERE. I DON'T KNOW IF ANYONE HERE
WANTS TO MAKE ANY COMMENT IN THAT REGARD, TO ADD TO THE
INFORMATION.

SIR?

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MR. EHSAN: THANK YOU, YOUR HONOR. HOUMAN EHSAN ON BEHALF OF AMYLIN.

YOUR HONOR, MR. THOMPSON RECOUNTED THE HISTORY
RELATIVELY CONSISTENT WITH OUR POSITION, BUT I DO WANT TO JUST
FLAG ONE MORE ISSUE FOR THE COURT. THE SUBPOENAS SERVED ON THE
UNIVERSITY OF TEXAS ARE ELEVEN SUBPOENAS SET FOR DEPOSITIONS
BEGINNING IN EARLY APRIL AND RUNNING TOWARD MID APRIL. WE
THINK THAT IS WELL, REGARDLESS OF THE POSITION THAT THE
TEXAS A.G.'S OFFICE IS GOING TO TAKE ON THE BURDEN IMPOSED BY
THESE SUBPOENAS ON VARIOUS FOLKS, INCLUDING CERTIFIED PUBLIC
ACCOUNTANTS AT THE UNIVERSITY OF TEXAS, WE DO THINK THAT THE
POTENTIAL ABILITY FOR PLAINTIFFS TO SUPPLEMENT THEIR EXPERT
REPORTS BY VIRTUE OF CLAIMING THAT ELEVEN SUBPOENAS ARE
OUTSTANDING MAY BE SKEWING THE FACTUAL RECORD A BIT. AND
DEFENDANTS WOULD LIKE TO RESERVE THEIR RIGHTS TO BRING UP
BEFORE THE COURT WHETHER OR NOT THESE SUBPOENAS WERE ACTUALLY
TIMELY GIVEN; THAT THE DISCOVERY CUTOFF FOR FACT DISCOVERY IN
THIS CASE HAS LONG SINCE BEEN CLOSED.

THE COURT: CERTAINLY. I WOULD RESERVE ANY
OBJECTIONS YOU HAVE OR ANY UNEXPRESSED POSITIONS BY THE
PLAINTIFFS ON THE ISSUE. WE UNDERSTAND THERE IS AN ISSUE
PERHAPS BREWING AND THAT IS AS FAR AS IT WILL GO FOR NOW. BUT
I APPRECIATE YOUR COMMENTS ON THAT.

AND I TAKE IT THAT THE TEXAS A.G. WILL PROBABLY SEEK RELIEF IN THE APPROPRIATE DISTRICT IN TEXAS, I'M GUESSING, IF THEY ARE GOING TO TRY TO STOP THE PROCESS, BUT MAYBE NOT.

MR. EHSAN: WELL, IN THEORY, BASED ON MY

UNDERSTANDING, THEY COULD SEEK THAT RELIEF EITHER IN TEXAS OR HERE, DEPENDING ON THE CIRCUMSTANCES.

THE COURT: I FIGURE THEY WANT THE HOME COURT

ADVANTAGE SO THEY WILL PROBABLY DO IT THERE. BUT THAT DISTRICT

DOES HAVE THE RIGHT, UNDER RULE 45, TO DEFER AND SEND THEM OUT

TO ME. SO WE'LL SEE.

MR. EHSAN: THANK YOU, YOUR HONOR.

THE COURT: THANK YOU FOR TELLING ME YOUR CONCERNS.

YES, SIR, MR. THOMPSON.

2.0

MR. THOMPSON: AND I'M NOT GOING TO ADDRESS ANYTHING FACTUALLY. AND I UNDERSTAND THAT THEY ARE RESERVING THEIR RIGHTS. BUT JUST AS TO THE BURDEN ON THE UNIVERSITY OF TEXAS, I WANTED TO SAY THAT I DID SEND AN E-MAIL TO THEIR CHIEF LEGAL OFFICER, SINCE WE HAD SERVED ELEVEN OF THE SUBPOENAS.

AND THE REASON WE DID THAT IS BECAUSE WE HAVE BEEN RUNNING AROUND THE WORLD, LITERALLY, TRYING TO FIND THESE SLIDES SO WE COULD SCAN THEM. AND I LET HIM KNOW THAT WE SERVED ELEVEN SUBPOENAS SO THAT WE COULD GET THAT INFORMATION, BUT THAT MY INTENTION WAS THAT WE WOULD NARROW THAT DOWN DRAMATICALLY WHEN HE HAD THE OPPORTUNITY TO TALK TO THOSE ELEVEN FOLKS AND FIGURE OUT IF IT'S REALLY JUST ONE OR TWO THAT WE NEED TO TALK TO.

I DO NOT WANT TO PUT A BURDEN ON THE UNIVERSITY OF TEXAS, AND I'VE REACHED OUT TO THEM TO LET THEM KNOW THAT.

THE COURT: WELL, THANK YOU FOR THAT FURTHER

SUPPLEMENTATION.

2.0

AND THEN WHY DON'T WE TURN -- UNLESS THERE IS SOMETHING ELSE -- TO THE THYROID CASES.

AND I THINK, MR. KING, YOU WERE GOING TO TAKE THE FIRST STEP ON THAT?

MR. KING: YES, YOUR HONOR. KENNETH KING FOR ELI LILLY AND COMPANY. AS WE DID LAST TIME, I WANTED TO BEGIN BY GIVING YOUR HONOR A BRIEF STATUS REPORT OF THE INVENTORY.

LILLY AND AMYLIN CURRENTLY HAVE A TOTAL OF 71 THYROID CANCER CASES. 63 HAVE BEEN SERVED, EIGHT HAVE NOT BEEN SERVED. AND I KNOW YOUR HONOR WAS FOCUSED ON THE CASES THAT HAD NOT BEEN SERVED, LAST TIME.

THAT ISSUE HAS PRETTY MUCH BEEN RESOLVED. AS WE SAID WE WOULD DO, WE PROVIDED A LIST OF UNSERVED CASES TO MR. THOMPSON. OF THE EIGHT CURRENTLY NOT SERVED, ALL BUT TWO HAVE BEEN FILED ONLY RECENTLY. OF THE TWO CASES THAT HAVE NOT BEEN SERVED AND HAVE NOT BEEN FILED RECENTLY, WE WILL PROVIDE THOSE — IDENTIFY THOSE TO THE PLAINTIFFS AND SEE IF WE CAN RESOLVE THAT ISSUE.

THE COURT: OKAY.

MR. KING: YOUR HONOR SIGNED THE IMPLEMENTING ORDER FOR THE PLAINTIFFS' FACT SHEET ON MARCH 2ND. AND, THEREFORE, WITHIN 75 DAYS WE ANTICIPATE RECEIVING FIELD DATA COMPLETED PLAINTIFFS' FACT SHEETS. HOPEFULLY, IF THEY ARE READY EARLY, WE CAN RECEIVE THEM ON A ROLLING BASIS. FOR CASES FILED AFTER

2.0

MARCH 2ND, WE'D RECEIVE THEM 45 DAYS PURSUANT TO YOUR HONOR'S ORDER.

THERE IS AN ISSUE THAT HAS ARISEN AS A RESULT OF AN ORDER YOUR HONOR ISSUED IN THE SAVINAR CASE, AND I WANTED TO CLEAR THAT ISSUE UP TODAY, IF I COULD.

THE SAVINAR CASE -- IT'S S-A-V-I-N-A-R -- DOCKET

NUMBER 14CV1512, THAT IS A THYROID CANCER CASE. AND YOUR HONOR

ISSUED AN ORDER. IT'S ORDER NUMBER -- OR DOCUMENT SIX ON THE

COURT'S DOCKET. IT'S DATED FEBRUARY 27TH, 2015. AND IT'S AN

ORDER ORDERING LILLY AND AMYLIN TO ANSWER THE COMPLAINT.

AND WHAT I WANT TO CLARIFY IS THIS, YOUR HONOR. LAST JULY YOUR HONOR STAYED THE ANSWERS TO THE THYROID CANCER CASES PENDING CREATION OF MASTER PLEADINGS.

ON AUGUST 14TH, YOUR HONOR, AT THE CONFERENCE, STATED THAT THE THYROID CASES WOULD TRAIL BEHIND THE PANCREATIC CANCER CASES, IN EFFECT STAYING THE CASES.

AT THE LAST CONFERENCE, FEBRUARY 2, YOUR HONOR
ESSENTIALLY LIFTED THAT STAY WITH RESPECT TO THE PLAINTIFFS'

FACT SHEETS. BOTH PLAINTIFFS AND DEFENDANTS WERE UNDER THE

IMPRESSION THAT THE STAY ON ANSWERS WAS STILL IN EXISTENCE, AND

THAT IS WHY THE SAVINAR CASE WAS NOT ANSWERED.

THE COURT: WELL, IS IT THE PREFERENCE OF THE DEFENSE
TO HAVE THAT MATTER STAYED AS THINGS CONTINUE TO DEVELOP AT
THIS POINT?

MR. KING: WELL, I THINK AS LONG AS PLAINTIFFS' FACT

2.0

SHEET DISCOVERY IS ONGOING WE WOULD BE CONTENT TO HAVE THE

ANSWER PROCESS STAYED, AS WELL, AND I CAN SPEAK FOR LILLY AND

AMYLIN.

THE COURT: HOW ABOUT FROM THE PLAINTIFFS'

STANDPOINT? I DON'T KNOW THAT I MADE THAT CONNECTION AT THE

TIME WHEN WE LIFTED THE STAY. I DIDN'T THINK THROUGH IT, SO MY

APOLOGIES. BUT WOULD IT BE IN THE PLAINTIFFS' INTEREST TO STAY

THE ANSWERS AS THESE EARLY PROCEEDINGS CONTINUE?

MR. SHKOLNIK: WE WOULD AGREE WITH THAT, YOUR HONOR.

MR. THOMPSON: YOUR HONOR, RYAN THOMPSON. WE HAVE

NO OBJECTION TO THAT AT ALL. WE THINK IT MAKES SENSE TO

PROCEED ALONG THAT PATH. AND IF THE COURT IS AMENABLE TO THAT,

WE ARE, AS WELL.

AND THEN TO BACKTRACK JUST A SECOND TO MR. KING'S DISCUSSION RELATED TO THE UNSERVED THYROID CASES. I WOULD, AGAIN, OFFER MY SERVICES TO HELP FACILITATE SERVICE AND WORK WITH PLAINTIFFS' COUNSEL TO GET THOSE SERVED. I THINK WE WERE PRETTY SUCCESSFUL IN GETTING THE MAJORITY DONE THE FIRST TIME, WORKING TOGETHER, AND I WOULD BE HAPPY TO DO THAT AGAIN.

THE COURT: OKAY. SO GIVEN THIS CONVERSATION, I WILL ISSUE AN ORDER STRIKING DOCUMENT SIX, RELIEVING THE OBLIGATION TO ANSWER IN SAVINAR, AND MEMORIALIZING THE CONTINUED STAY, GENERALLY, IN THE THYROID CASES, SUBJECT TO FURTHER ORDER. AND THAT SHOULD SOLVE THAT. AND MY APOLOGIES FOR CAUSING THE PROBLEM.

1	ANYTHING ELSE TO REPORT AT THIS POINT, MR. KING, ON
2	THE DEFENSE SIDE?
3	MR. KING: I DO HAVE A REQUEST, YOUR HONOR.
4	THE COURT: YEAH.
5	MR. KING: AN ADMINISTRATIVE ONE. THE ORDERS,
6	GENERALLY, IN THE THYROID CANCER CASES, HAVE BEEN UNDER THE
7	CHILDRESS CAPTION, AS YOUR HONOR KNOWS. AND WE WOULD ASK THAT
8	SUCH ORDERS BE PROPAGATED TO THE INDIVIDUAL THYROID CANCER
9	CASES, AS WELL, TO RELIEVE ANY CONFUSION THAT MAY BE CAUSED.
10	FOR EXAMPLE, A PLAINTIFFS' LAWYER WHO HAS A CASE, AN
11	ISOLATED THYROID CANCER CASE, MAY NOT RECEIVE A GENERAL AN
12	ORDER APPLYING TO THE CASES GENERALLY IF IT APPEARS ONLY UNDER
13	THE CHILDRESS CAPTION.
14	THE COURT: OKAY. I DON'T THINK THERE IS ANY REASON
15	WE SHOULDN'T DO THAT; RIGHT? WE CAN ADMINISTRATIVELY FIX THAT.
16	MR. KING: THANK YOU, YOUR HONOR.
17	THE COURT: SO THEY WILL ALL BE COPIED FOR ALL OF THE
18	COORDINATED CONSOLIDATED CASES.
19	AND IF THAT IS IT FOR YOU, MR. KING, ANYBODY ON THE
20	PLAINTIFFS' SIDE HAVE ANYTHING ELSE TO ADD ON THESE CASES?
21	MR. SHKOLNIK: YOUR HONOR
22	MR. THOMPSON: NOTHING FROM PLAINTIFFS, YOUR HONOR.
23	THE COURT: MR. THOMPSON SAYS NO AND MR. SHKOLNIK
24	CONCURS.
25	WOULD IT BE USEFUL TO SET AN APRIL 2ND STATUS FOR THE

1	THYROID IN CONJUNCTION WITH WHAT WE'RE DOING WITH THE MDL, JUST
2	TO TALK ABOUT ANYTHING THAT MAY BE AFOOT?
3	MR. KING: YES, YOUR HONOR. SURE.
4	MR. SHKOLNIK: YES, YOUR HONOR.
5	THE COURT: OKAY. ALL RIGHT. SO BOTH CASES WILL BE
6	ON FOR STATUS APRIL 2ND AT 2:00. THE MOTIONS ARE SUBMITTED AS
7	INDICATED, WITH AN ORDER TO FOLLOW AS SOON AS REASONABLY
8	POSSIBLE.
9	AND WE'LL FIX THE SAVINAR ORDER AS WE'VE TALKED
10	ABOUT.
11	IS THERE ANYTHING ELSE, THEN, FOLKS?
12	MR. SHKOLNIK: NOTHING FROM THE PLAINTIFFS.
13	THE COURT: ALL RIGHT. THANK YOU ALL VERY MUCH FOR
14	THE EXTENDED DISCUSSION ON THE MOTIONS, THE CASE IN GENERAL.
15	AND YOUR CONTINUED PROFESSIONALISM AND COOPERATION IS MUCH
16	APPRECIATED.
17	SO THE MATTER IS SUBMITTED. WE'LL TALK TO YOU IN
18	APRIL AND YOU WILL HEAR FROM ME IN THE MEANTIME. YOU-ALL TAKE
19	CARE. WE ARE IN RECESS.
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MARCH 12, 2015

## AVAILABLE AT PUBLIC TERMINAL FOR VIEWING ONLY (PROCEEDINGS CONCLUDED AT 3:42 P.M.) CERTIFICATION I HEREBY CERTIFY THAT I AM A DULY APPOINTED, QUALIFIED AND ACTING OFFICIAL COURT REPORTER FOR THE UNITED STATES DISTRICT COURT; THAT THE FOREGOING IS A TRUE AND CORRECT TRANSCRIPT OF THE PROCEEDINGS HAD IN THE AFOREMENTIONED CAUSE ON MARCH 12, 2015; THAT SAID TRANSCRIPT IS A TRUE AND CORRECT TRANSCRIPTION OF MY STENOGRAPHIC NOTES; AND THAT THE FORMAT USED HEREIN COMPLIES WITH THE RULES AND REQUIREMENTS OF THE UNITED STATES JUDICIAL CONFERENCE. DATED: MARCH 18, 2015, AT SAN DIEGO, CALIFORNIA. JEANNETTE N. HILL, OFFICIAL REPORTER, CSR NO. 11148 2.0 MARCH 12, 2015